

# Exhibit 151



IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS  
STATE OF MISSOURI

GAIL LUCILLE INGHAM, et al.,	)	
	)	
<i>Plaintiffs,</i>	)	Case No.: 1522-CC10417-01
v.	)	
	)	
JOHNSON & JOHNSON, et al.,	)	Division: 10
	)	
<i>Defendants.</i>	)	

**AFFIDAVIT OF PATRICIA GRIPKA MOORMAN, M.S.P.H., PH.D.**

I, Patricia Moorman, do hereby declare as follows:

1. I am over the age of 18 years of age and otherwise competent to testify to the matters contained in this affidavit.
2. I have been retained by the Plaintiffs in this case as an expert witness. I have reviewed Defendants' Motion to Exclude Plaintiffs' Experts' General Causation Opinions. I have also reviewed the affidavit by Gregory Diette, M.D. that was attached as exhibit 12 to Defendants' Motion.
3. The following are my responses to some of the points that Dr. Diette attempts to make in his affidavit, attached as Exhibit 12 to Defendants' Motion. My failure to address a specific point made by Dr. Diette should not be interpreted as an expression of agreement with such point. All statements of fact are true and correct, and all opinions are based on, among other things, my training and experience, research, and documents and other evidence produced to me in this case. The following are my responses to Dr. Diette's affidavit:



**Point 11: "it (the association between talc use and ovarian cancer) is present only in population-based case-control studies, which are incapable of proving causation"**

This opinion ignores the long history of using observational studies, both case-control and cohort studies, to assess causation between harmful exposures and cancer. In fact, the 1950 landmark epidemiologic studies describing the increased risk of lung cancer in cigarette smokers were case-control studies. (Wynder E, Graham E, 1950; Doll R, Hill A. 1950). Given that it is impossible to conduct experiments on humans by intentionally exposing them to suspected carcinogens, in virtually all situations where one is trying to determine if an exposure causes cancer, scientists are relying on observational studies (both case-control and cohort studies) in humans to make a determination of causality.

It is widely-accepted that case-control studies are a valid study design for studying cancer etiology and are especially well-suited for cancers that are less common. Of all the studies of talc and ovarian cancer, the African American Cancer Epidemiology Study (AACES) is the one that was most recently initiated, with funding from the National Cancer Institute (NCI) and data collection commencing in 2010. When Dr. Schildkraut and I submitted the grant application in 2009, a reviewer expressed the opinion that a prospective cohort would be a preferred design. We successfully argued that it would be impossible to do a well-powered study of ovarian cancer in African American women in a timely manner using a prospective cohort design. In particular, we pointed out that the Black Women's Health Study, a prospective cohort with ~60,000 participants, had fewer than 100 cases of ovarian cancer within the cohort after approximately 15 years of follow-up. Therefore a case-control study was the only feasible design for studying ovarian cancer risk factors in African-American women in a reasonable time frame. The fact that our application to conduct a population-based case-control study was favorably reviewed in study section (peer-reviewed) and approved by the NCI National Cancer Advisory Board for funding is a clear indication that the case-control design is considered a reasonable and valid approach to studying cancer etiology.

It is true that the more ideal scenario would permit experimental studies in which individuals are randomly assigned to an exposure or control group and then followed to see if the disease occurs more frequently in the exposed group. It is obviously unethical as well as logistically impossible to use a randomized experimental study to determine if an exposure causes cancer.

**Point 12: "There are two types of epidemiologic studies at issue here: cohort studies and case-control studies. Cohort studies are widely regarded as more reliable than retrospective case-control studies because they are not susceptible to recall bias . . . ."**  
**"Due to the ability of the cohort studies to assess exposure at baseline instead of relying on recall, they are better suited to detect risks from exposure to an agent."**

Dr. Diette never acknowledges that cohort studies are also susceptible to bias, and in the situation of talc and ovarian cancer, the biases in the cohort studies are likely to



result in an attenuation of the relative risk. Specifically, each of the cohort studies (Sister Study (Gonzalez, 2016), Nurses' Health Study (Gertig, 2000; Gates, 2008), Women's Health Initiative (Houghton, 2014) had incomplete exposure assessment. *Talc use was assessed at one point only and there was no additional assessment of talc use during the 6 to 20+ years of follow-up of these studies.* This likely resulted in non-differential misclassification of the exposure (i.e., the misclassification of talc use would have occurred to a similar degree in women who subsequently developed ovarian cancer and those who did not). In general, non-differential misclassification will tend to bias results towards the null, meaning that the relative risk is not as strong as if all women were accurately classified as to their exposure.

The assessment of talc exposure was particularly weak in the Sister Study (Gonzalez, 2016). The study participants were queried about talc use only during the previous year, so they captured neither any use prior to one year before the interview nor any use in the ~ 6 years of follow-up between the time of the interview and when the data analysis was performed. This study reports a prevalence of use of talc of ~14%, which contrasts with the prevalence of talc use of ~40% reported in most other US studies including the Nurses' Health Study and the Women's Health Initiative. So there is quite compelling evidence of considerable misclassification of exposure in this study.

Dr. Diette's statement that "cohort studies ... assess exposure at baseline instead of relying on recall" is also somewhat misleading. Both the Nurses' Health Study and the Women's Health Initiative asked study participants to recall their use of talc over their lifetime up to the point of the interview. The Nurses' Health Study participants were aged 36 to 61 years when talc use was assessed in 1982 and the Women's Health Initiative participants had a mean age of 63 years at enrollment, therefore these studies also relied on women's recall of use over a long period of time, and there was likely some inaccuracy in their recall. Inaccurate recall of past use would likely result in non-differential misclassification of the exposure, with the likely result of an attenuation of the true relative risk.

**Point 15: "Interestingly, [the Gonzales Study] separately found an association between douching and ovarian cancer, suggesting that douching (which sometimes accompanies perineal talc use) may be a confounding variable that has not sufficiently been accounted for in past studies."**

In addition to the points made above in relation to the serious concerns about inadequate exposure assessment in the Gonzalez study, it should be pointed out that despite the large size of the cohort, the study involved only 154 cases of ovarian cancer and only 17 of those had exposure to talc. The study was not designed to study ovarian cancer and had very limited statistical power to address this outcome.

Regarding the point about douching being a potential confounder, the authors of this paper write "By contrast, talc use during the 12 months prior to study entry was associated with reduced risk after the same confounder adjustments (HR:0.73 CI: 0.44,



1.2) and there was a negligible change in the estimated effect with additional adjustment for douching (HR: 0.70 CI 0.42, 1.1)". If douching was a confounder of the association between talc use and ovarian cancer, one would have expected a substantial change in the hazard ratio once they adjusted for douching. The statement in their paper clearly indicates that their data do not show that their talc results were confounded by douching.

Furthermore, douching as a potential confounder has been addressed in at least two other studies. Hartge et al. (1983) reported "Also, we noted that cases and controls were equally likely to report douching. Since reporting of use of douches might be subject to the same recall biases as talc use, this observation suggests that little recall bias operated." The fact that cases and control were equally likely to report douching indicates that this factor would not be a confounder of the association between talc use and ovarian cancer. Harlow et al. (1992) controlled for douching as a potential confounder and still reported a statistically significant increased risk associated with talc use. As a whole, this evidence discounts the possibility that the association between talc use and ovarian cancer is due to confounding by douching.

#### **Point 17: Houghton study**

Another possible concern with the Houghton study is that the mean age of the participants at enrollment was 63 years, which is older than the median age of diagnosis of ovarian cancer. While it is unclear how using an cohort of older women might have affected the results, it is a point to bear in mind when considering an exposure that for many women began in their teens or 20s.

#### **Point 19: "none of the cohort studies - which have collectively examined more than 200,000 women"**

As described above in relation to the Gonzalez study, even a large cohort may be inadequately powered to detect an association, especially for a relatively rare cancer like ovarian cancer and for an exposure like talc where the expected relative risk is approximately 1.25 to 1.3. Despite involving >40,000 women, there were only 154 ovarian cancer cases in this study and only 17 of them reported exposure to talc, a number that clearly makes it difficult to make reliable conclusions from this study. As described in a 2016 article by Narod, et al, the lack of a significant overall association between ever use of talc and ovarian cancer in the cohort studies may be due to the fact that despite the large size of the cohorts, the studies were not adequately powered to detect a relative risk of approximately 1.2.

#### **Point 21: recall bias in AACES study**

Recall bias is an acknowledged possible bias in any case-control study, and it is discussed as a possible limitation in most published studies. It is worth noting that it is



quite standard in the epidemiologic and medical literature for authors to describe *possible* limitations of their studies in the discussion section of the paper, regardless of whether they believe those limitations had a substantial influence on the findings.

The question is whether recall bias is enough of a problem to account for the 25-30% increased risk for ovarian cancer that has been reported for talc use in multiple meta-analysis. There are studies that answer this question.

In most case-control studies of ovarian cancer, the participants complete a very extensive questionnaire –often more than 50 pages of questions addressing a wide range of factors, including some that would be expected to increase risk and some to decrease risk. Women are not told in advance of the interview what factors they will be asked about except in very general terms such as reproductive history, medical history or lifestyle characteristics. The women taking part in the case-control studies would not have known in advance of the interview that they would be asked about talc use. Since there had not been widespread publicity about talc use and ovarian cancer during the timeframe when nearly all of the studies collected data, it is difficult to imagine that the cases gave more thought to their use of talc than the controls, resulting in sufficient recall bias to account for the 25-30% increased risk.

Empirical evidence that recall bias is not likely to have a substantial effect on study findings in most circumstances comes from a study reported by Lanza, et al. (2016) in which they compared estimates from case-control studies and cohort studies in meta-analyses. The 23 meta-analyses that they examined covered a variety of interventions and outcomes and each included both case-control and cohort studies. Their overall conclusion is that estimates did not differ significantly between case-control studies and cohort studies. This study provides empirical evidence that although case-control studies theoretically have a higher risk for recall bias, in practice there are not likely to be significant differences in the estimates of the relative risks between case-control and cohort studies.

In Cramer et al.'s 2016 paper, they provide a detailed discussion of the possibility of recall bias and why it is an unlikely explanation for the association between talc and ovarian cancer. The points the authors made include: 1) the degree of misclassification that would need to exist to nullify the association is not supported by data on differences in risk factor information collected retrospectively and prospectively, 2) ORs are generally lower in studies which asked about "ever use" of talc, compared with those that specified regular use, and 3) ORs from recent studies are lower than those from earlier studies.

As we have acknowledged, the AACES study did collect data during the timeframe when there was more publicity about talc use and ovarian cancer, and the association was stronger among the women who were interviewed more recently. It is important to note that the association between talc use and ovarian cancer was attenuated but not



eliminated when we analyzed only the women interviewed in the earlier time frame, which indicates that the association was not due entirely to recall bias.

**Point 22: Hospital-based case-control studies**

It is true that these studies do show a broad range of estimates in the relative risks, but there is no discussion of potential biases and limitations in the hospital-based studies. With the exception of the Wong study (Wong, 1999), the number of cases in the individual studies was small (46 to 217), so the lack of statistically significant findings even in the studies reporting ORs of 1.3 to 1.7 is not surprising. The Wong study, with 499 cases, was better powered statistically, however it has an important limitation in its design, specifically in its choice of controls. When conducting a case-control study (whether hospital or population-based), investigators identify individuals with the disease, ovarian cancer in this case, and select a group of individuals without the disease as a control group. As described in the standard epidemiologic textbook, *Modern Epidemiology*, "Controls should be selected from the same population – the source population or study base – that gives rise to the cases". In the Wong study, the controls for the ovarian cancer cases were "female patients treated for nongynecologic malignancies during the same period". It is difficult to make the argument that other cancer patients represent the source population from which the ovarian cancer cases arose, so arguably this was a poor choice of a control group and could have led to biased findings. Another of the hospital-based studies, the Tzonou study (Tzonou, 1993) which reported a relative risk of 1.05 also had a significant limitation. This study was conducted in Greece and the overall prevalence of talc use in the study population was ~3.5%. Given the small sample size and the low prevalence of exposure, this population was ill-suited to study the relation between talc use and ovarian cancer.

**Point 23: "In summary, 11 of the 25 population-based case-control studies, including several by Dr. Moorman, do not show a statistically significant association and none of the hospital-based studies do."**

When considering the body of evidence on a topic, the statistical significance of findings from individual studies is of course something to be considered, however the overall evaluation of the association should not simply be a count of how many studies were statistically significant. Especially when one is looking at relative risks in the range of 1.2 to 1.3 and some of the studies are relatively small (either in total sample size or total number of cases), it would be expected that some studies will not be statistically significant. In many cases, talc use was one of many exposures examined in a particular study and the study was not specifically designed and powered to look at talc. Part of the rationale for performing meta-analyses is to combine data from all relevant studies (statistically significant or not) to come up with an overall estimate of risk that is more statistically robust.



To illustrate this point, it is useful to compare the data from the talc and ovarian cancer studies to the data on passive smoking (also known as second-hand smoke or environmental tobacco smoke) and lung cancer. Like talc, passive smoke is a very common exposure in the population that can only be assessed retrospectively through self-report, making it difficult to quantify the precise level of exposure. Numerous epidemiologic studies have assessed the association between passive smoke exposure and many of the individual studies reported odds ratios or relative risks that were not statistically significant. Nonetheless, IARC has judged on the totality of evidence that there is a causal association between passive smoke exposure and lung cancer. The epidemiologic evidence on passive smoke exposure and lung cancer was summarized in a 2007 meta-analysis by Taylor, et al. (2007), which combined data from 55 studies and reported a statistically significant pooled relative risk of 1.27 (95% CI 1.17-1.37). The relative risks from individual studies ranged from 0.66 to 2.57, with 44 of the 55 (80%) individual studies reporting a relative risk or odds ratio greater than 1. Only 10 of the 55 (18%) studies reported statistically significant odds ratios or relative risks.

The data from the 2017 meta-analysis of talc and ovarian cancer by Berge et al. reported a pooled relative risk of 1.22 (95% CI 1.13-1.30) with values from individual studies ranging from 0.70 to 3.90. Twenty-four of the 27 (89%) studies reported a relative risk or odds ratio greater than 1, and statistically significant associations were reported in 13 of the 27 (48%) of the studies. So, as compared to the epidemiologic data on the well-accepted causal association between passive smoke exposure and lung cancer, the epidemiologic data on talc and ovarian cancer shows an overall relative risk estimate of similar magnitude, with a greater proportion of studies reporting relative risks >1 and a greater proportion reporting statistically significant associations.

Other examples of exposure-disease associations that are considered causal associations by IARC, have relative risks in the same range as talc and ovarian cancer, and meta-analyses conclude there is a statistically significant overall association even when a substantial number of the studies included in the meta-analysis did not have statistically significant findings include red or processed meat consumption and colorectal cancer, menopausal estrogen use and breast cancer, oral contraceptives and breast cancer, and residential radon exposure and lung cancer. (IARC, 2008, 2009, 2012; Chan, 2011; Shah, 2005; Collaborative Group on Hormonal Factors, 1996; Zhang, 2012).

#### **Point 24: Meta-analysis summary**

Dr. Diette's summary of the meta-analyses ignores results and conclusions from the most recently published meta-analysis by Penninkilampi and Eslick (2018). Specifically, statistically significant associations with serous invasive ovarian cancer (the most common histologic type of ovarian cancer) were found in both case-control and cohort studies (Table 2). Their overall conclusions include "In general, there is a consistent association between perineal talc use and ovarian cancer" and "While the results of case-control studies are prone to recall bias, especially with intense media attention following the commencement of litigation in 2014, the confirmation of an association in



cohort studies between perineal talc use and serous invasive ovarian cancer is suggestive of a causal association.”

4. The following are my responses to some of the points that Defendants attempt to make in their motion to strike my general causation opinions. My failure to address a specific point made by Defendants should not be interpreted as an expression of agreement with that point.

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Regarding my oversight in failing to disclose that I was a plaintiffs’ expert to the journal for a recently published paper, this was a non-intentional oversight on my part, which I acknowledged in my deposition. I was one of ~40 authors on a paper that examined about 20 different exposures. I contacted the journal’s editor immediately after it was brought to my attention and was told they would include a correction to the paper. It was clear to me that the editor agreed it should be corrected but did not think it was a serious concern.

#### Page 61

The point that an increase in other gynecologic cancers . . . such as vaginal cancer, cervical cancer, uterine cancer or fallopian tube cancer would be expected if cosmetic talc is a carcinogen that travels to the ovaries via the reproductive tract is not a valid argument. Carcinogens typically do not cause cancer across all body sites. It is very common that associations between exposures and cancers differ across different body organs, even when considering those that might be thought to have similarities, e.g. hormone-related cancers. To give just a few examples:

- Oral contraceptives are associated with a reduced risk for ovarian and endometrial cancer but increased risk for breast and cervical cancer.
- Menopausal estrogen increases risk for ovarian cancer and endometrial cancer more than menopausal estrogen plus progestin, but the converse is true for breast cancer.
- Smoking increases risk for lung and oral cavity cancers but is associated with a reduced risk of endometrial cancer.

I think it’s worthwhile to address comments made throughout the documents indicating that many publications, including some of my own, do not describe the repeatedly observed association between talc and ovarian cancer as “causal”. In the May 2018 issue of the American Journal of Public Health, there are three



commentaries/editorials that address how investigators who conduct observational studies often avoid the use of “causal language” in their manuscripts, often at the request of co-authors, editors or reviewers.(Galea S and Vaughn RD; Hernan MA; Begg MD and March D, 2018). The message of these papers is that “causal” has become “a dirty word, the C-word that researchers have learned to avoid”. The authors argue that avoidance of causal language has been harmful to science, using the term “causal” can more accurately reflect the objectives of the research and there should be a move to reintroduce causal language into population health science research. These papers clearly articulate why very few of the papers or meta-analyses describe talc as a “cause” of ovarian cancer despite the multiple meta-analyses and individual studies indicating statistically significant associations between talc and ovarian cancer. Although the intent of these studies was to see if talc was a cause of ovarian cancer, the standards within the profession led most authors to avoid such terminology and instead use the “risk factor” or “association” terminology.

5. The following references support this rebuttal:

Begg MD, March D. Cause and association: missing the forest for the trees. *AJPH* 2018; 108: 620.

Berge W, Mundt K, Luu H, Boffetta P. Genital use of talc and risk of ovarian cancer: a meta-analysis. *Eur J Cancer Prev.* 2017.

Chan DS, et al. Red and processed meat and colorectal cancer incidence: meta-analysis of prospective studies. *PLoS One* 2011; 6: e20456.

Collaborative Group on Hormonal Factors in Breast C. Breast cancer and hormonal contraceptives: collaborative reanalysis of individual data on 53 297 women with breast cancer and 100 239 women without breast cancer from 54 epidemiological studies. *Lancet.* 1996;347(9017):1713-1727.

Cramer DW, Vitonis AF, Terry KL, Welch WR, Titus LJ. The Association Between Talc Use and Ovarian Cancer: A Retrospective Case-Control Study in Two US States. *Epidemiology.* 2016;27(3):334-346.

Doll R, Hill A. Smoking and carcinoma of the lung: preliminary report. *BMJ* 1950; 2: 739-48

Galea S, Vaughan RD. Moving beyond the cause constraint: a public health of consequence, May 2018. *AJPH* 2018; 108: 602-3.

Gates MA, Tworoger SS, Terry KL, et al. Talc use, variants of the GSTM1, GSTT1, and NAT2 genes, and risk of epithelial ovarian cancer. *Cancer Epidemiol Biomarkers Prev.* 2008;17(9):2436-2444.

Gertig DM, Hunter DJ, Cramer DW, et al. Prospective study of talc use and ovarian cancer. *J Natl Cancer Inst.* 2000;92(3):249-252.



Gonzalez NL, O'Brien KM, D'Aloisio AA, Sandler DP, Weinberg CR. Douching, Talc Use, and Risk of Ovarian Cancer. *Epidemiology*. 2016;27(6):797-802.

Harlow BL, Cramer DW, Bell DA, Welch WR. Perineal exposure to talc and ovarian cancer risk. *Obstet Gynecol*. 1992;80(1):19-26.

Hartge P, Hoover R, Leshner LP, McGowan L. Talc and ovarian cancer. *JAMA*. 1983;250(14):1844.

Hernan MA. The C-word: scientific euphemisms do not improve causal inference from observational data. *AJPH* 2018; 108: 616-619.

Houghton SC, Reeves KW, Hankinson SE, et al. Perineal powder use and risk of ovarian cancer. *J Natl Cancer Inst*. 2014;106(9).

IARC A review of human carcinogens. Part E: Personal habits and indoor combustions / IARC Working Group on the Evaluation of Carcinogenic Risks to Humans. Lyon, France 2009.

IARC A review of human carcinogens. Part A: Pharmaceuticals / IARC Working Group on the Evaluation of Carcinogenic Risks to Humans Lyon, France 2008.

IARC A review of human carcinogens. Part D: Radiation IARC Working Group on the Evaluation of Carcinogenic Risks to Humans Lyon, France 2012.

Lanza A, et al. Comparison of estimates between cohort and case-control studies in meta-analyses of therapeutic interventions: a meta-epidemiological study. *PLoS One* 2016; 11: e0154877.

Narod SA. Talc and ovarian cancer. *Gynecol Oncol*. 2016;141(3):410-412.

Penninkilampi R, Eslick GD. Perineal talc use and ovarian cancer. A systematic review and meta-analysis. *Epidemiology* 2018; 29: 41-49.

Schildkraut JM, Alberg AJ, Bandera EV, et al. A multi-center population-based case-control study of ovarian cancer in African-American women: the African American Cancer Epidemiology Study (AACES). *BMC cancer*. 2014;14:688.

Shah NR, et al. Postmenopausal hormone therapy and breast cancer: a systematic review and meta-analysis. *Menopause* 2005; 12: 668-78.

Taylor R, et al. Meta-analysis of studies of passive smoking and lung cancer: effects of study type and continent. *Int J Epidemiol* 2007; 36: 1048-1059.



Tzonou A, Polychronopoulou A, Hsieh CC, Rebelakos A, Karakatsani A, Trichopoulos D. Hair dyes, analgesics, tranquilizers and perineal talc application as risk factors for ovarian cancer. *Int J Cancer*. 1993;55(3):408-410.

Wong C, Hempling RE, Piver MS, Natarajan N, Mettlin CJ. Perineal talc exposure and subsequent epithelial ovarian cancer: a case-control study. *Obstet Gynecol*. 1999;93(3):372-376.

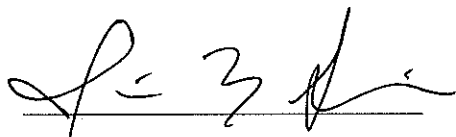
Wynder E, Graham E. Tobacco smoking as a possible etiologic factor in bronchogenic carcinoma. *JAMA* 1950; 143: 329-36

Zhang ZL et al. Residential radon and lung cancer risk: an updated meta-analysis of case-control studies. *Asian Pac J Cancer Prev* 2012; 13: 2459-65."

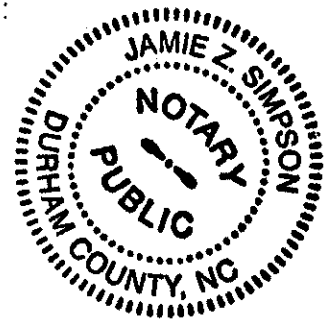
FURTHER AFFIANT SAYETH NOT.

  
PATRICIA MOORMAN, M.S.P.H., PH.D.

SWORN AND SUBSCRIBED TO before me this 21<sup>st</sup> day of May, 2018:

  
Notary

Commission expires: 9/8/22





# Exhibit 152



**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Adolescent Depression.

**Date:** October 28, 2005.

**Time:** 12 p.m. to 1 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Bethesda Marriott Suites, 6711 Democracy Boulevard, Bethesda, MD 20817.

**Contact Person:** Karen Sirocco, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301-435-0676, [siroccok@csr.nih.gov](mailto:siroccok@csr.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Epigenetic Changes in Mouse Skin Tumor Susceptibility.

**Date:** October 28, 2005.

**Time:** 12 p.m. to 1:30 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

**Contact Person:** Elaine Sierra-Rivera, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892, 301-435-1779, [riverase@csr.nih.gov](mailto:riverase@csr.nih.gov).

**Name of Committee:** Musculoskeletal, Oral and Skin Sciences Integrated Review Group, Musculoskeletal Tissue Engineering Study Section.

**Date:** October 31–November 1, 2005.

**Time:** 8 a.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

**Contact Person:** Jean Dow Sipe, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4106, MSC 7814, Bethesda, MD 20892, 301-435-1743, [sipej@csr.nih.gov](mailto:sipej@csr.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Conflicts in Biological Chemistry and Macromolecular Biophysics.

**Date:** October 31, 2005.

**Time:** 8 a.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

**Contact Person:** Donald L. Schneider, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4172, MSC 7806, Bethesda, MD 20892, (301) 435-1727, [schneidd@csr.nih.gov](mailto:schneidd@csr.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, F-13 Fellowship.

**Date:** October 31–November 1, 2005.

**Time:** 8 a.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications. and/or proposals.

**Place:** The Watergate, 2650 Virginia Avenue, NW., Washington, DC 20037.

**Contact Person:** John C. Pugh, PHD, Scientific Review Administrator, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3114, MSC 7808, Bethesda, MD 20892, (301) 435-2398, [pughjohn@csr.nih.gov](mailto:pughjohn@csr.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Cancer Diagnostic and Treatment SBIR/STTR.

**Date:** October 31–November 1, 2005.

**Time:** 8 a.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

**Contact Person:** Hungyi Shau, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, MSC 7804, Bethesda, MD 20892, 301-435-1720, [shauhung@csr.nih.gov](mailto:shauhung@csr.nih.gov).

**Name of Committee:** Oncological Sciences Integrated Review Group, Radiation Therapeutics and Biology Study Section.

**Date:** October 31–November 1, 2005.

**Time:** 8:30 a.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

**Contact Person:** Bo Hong, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301-435-5879, [hongb@csr.nih.gov](mailto:hongb@csr.nih.gov).

**Name of Committee:** Bioengineering Sciences & Technologies Integrated Review Group, Modeling and Analysis of Biological Systems Study Section.

**Date:** October 31–November 1, 2005

**Time:** 8:30 a.m. to 5 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

**Contact Person:** Malgorzata Klosek, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4188, MSC 7849, Bethesda, MD 20892, (301) 435-2211, [klosekm@mail.nih.gov](mailto:klosekm@mail.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Drug Discovery and Development SBIR/STTR

**Date:** October 31, 2005.

**Time:** 8:30 a.m. to 6 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** One Washington Circle Hotel, One Washington Circle, Washington, DC 20037

**Contact Person:** Sergei Ruvinov, PHD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301-435-1180, [ruvinser@csr.nih.gov](mailto:ruvinser@csr.nih.gov).

**Name of Committee:** Center for Scientific Review Special Emphasis Panel, Member Conflict: Surgery, Anesthesiology, and Trauma.

**Date:** October 31, 2005.

**Time:** 2 p.m. to 4 p.m.

**Agenda:** To review and evaluate grant applications.

**Place:** National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

**Contact Person:** Roberto J. Matus, MD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892, 301-435-2204, [matusr@csr.nih.gov](mailto:matusr@csr.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

**Dated:** October 6, 2005.

**Anthony M. Coelho, Jr.,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 05–20739 Filed 10–17–05; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 17, 2005, 1 p.m. to October 17, 2005, 2 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on September 30, 2005, 70 FR 57304–57305.

The meeting will be held on October 13, 2005. The meeting time and location remain the same. The meeting is closed to the public.

**Dated:** October 6, 2005.

**Anthony M. Coelho, Jr.,**

*Acting Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 05–20740 Filed 10–17–05; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Toxicology Program (NTP); Report on Carcinogens; Status of Nominations to the 12th Report on Carcinogens (RoC): Request for Comments and Nominations of Scientific Experts

**AGENCY:** National Institute of Environmental Sciences (NIEHS), National Institutes of Health (NIH), HHS.



**ACTION:** Request for Comments and Nominations of Scientific Experts.

**SUMMARY:** The NTP invites public comments on an updated list of nominations proposed for review in the 12th RoC and the nomination of scientists who have expertise and/or knowledge relevant to the evaluation of carcinogenicity for these nominations (see **SUPPLEMENTARY INFORMATION**).

Information on the nominations under consideration for the RoC can be obtained at the NTP Web site <http://ntp.niehs.nih.gov> (select "Report on Carcinogens") or by contacting Dr. C.W. Jameson at the address provided below.

**DATES:** Comments and nominations will be accepted until November 17, 2005.

**ADDRESSES:** All correspondence should be directed to Dr. C. W. Jameson, National Toxicology Program, Report on Carcinogens, 79 Alexander Drive, Building 4401, Room 3118, P.O. Box 12233, Research Triangle Park, NC 27709; phone: (919) 541-4096, fax: (919) 541-0144, e-mail: [jameson@niehs.nih.gov](mailto:jameson@niehs.nih.gov).

**SUPPLEMENTARY INFORMATION:****Background**

This notice provides an update on the current status of and/or additions to the list of nominations identified in earlier **Federal Register** notices relevant to the 12th RoC [69FR28940 (May 19, 2004) and 69FR62276 (October 25, 2004)]. All but the newly identified nomination of formaldehyde were announced in earlier **Federal Register** notices. Any additional nominations for the 12th RoC or modifications to the nominations in the attached table will be announced in future **Federal Register** notices.

**Request for Comments on Nominations to the RoC**

The following table identifies the nominations that the NTP has under consideration for review as either a new listing in the RoC or as a change in the current listing. These nominations are provided with their Chemical Abstracts

Services (CAS) Registry numbers (where available) and pending review action. The NTP solicits public input on these nominations and asks for relevant information concerning their carcinogenicity as well as current data on production, patterns of use, or human exposure. The NTP also invites interested parties to identify any scientific issues related to the listing of a specific nomination in the RoC that they feel should be addressed during the reviews. Individuals who submitted comments in response to the May 19, 2004 **Federal Register** (69FR28940) and/or the October 25, 2004 **Federal Register** notice (69FR62276) need not re-submit their comments as they are already part of the public record. Individuals submitting public comments are asked to include relevant contact information [name, affiliation (if any), address, telephone, fax, and e-mail] and sponsoring organization, if applicable. Written submissions will be made available on the NTP Web site as they are received (<http://ntp.niehs.nih.gov>/select "Report on Carcinogens") and added to the public record.

**Request for Nominations of Scientific Experts**

The NTP solicits nominations of scientists who have expertise and/or knowledge relevant to the evaluation of carcinogenicity for the selected nominations. These scientists should have expertise in various aspects of toxicology, epidemiology, carcinogenesis, or other relevant areas of science (e.g., genetic toxicity, metabolism, etc.) and/or experience with the agent being reviewed. The experts may be used to write and/or review the background documents prepared on selected nominations. Nominations of scientists should include contact information for the nominee [name, affiliation (if any), address, telephone, fax, and e-mail], the specific nominated agent(s) (listed in the table below) for which they are being recommended as an expert, and a

curriculum vitae (if possible). Contact information for the nominator must also be provided.

**Additional Nominations Encouraged**

The NTP solicits and encourages the broadest participation from interested individuals or parties in nominating agents, substances, or mixtures for review for future RoCs. Nominations should contain a rationale for review. Appropriate background information and relevant data [e.g., journal articles, NTP Technical Reports, International Agency for Research on Cancer (IARC) listings, exposure surveys, release inventories, etc.] that support the review of a nomination should be provided or referenced when possible. Contact information for the nominator should also be included [name, affiliation (if any), address, telephone, fax, and e-mail].

**Background Information on the Report on Carcinogens**

The RoC is a congressionally mandated document [Section 301(b)(4) of the Public Health Services Act, 42 U.S.C. 241(b)(4)], published by the Secretary of Health and Human Services (HHS), that identifies agents, substances, mixtures, or exposure circumstances (collectively referred to as "substances") that may pose a carcinogenic hazard to human health. The Secretary, HHS, has delegated responsibility for preparing the draft report to the NTP. Substances are listed in the RoC as either known to be a human carcinogen or reasonably anticipated to be a human carcinogen. Review of nominations (substances that are under consideration for listing or removing from the RoC) involves a multi-step scientific review process with opportunity for public comment.

Dated: October 6, 2005.

**Samuel H. Wilson,**

*Deputy Director, National Institute of Environmental Health Sciences.*

**STATUS OF NOMINATIONS TO BE REVIEWED FOR THE REPORT ON CARCINOGENS**

Nomination/CAS No.	Primary uses or exposures	Nominator	Basis for nomination	Status
<sup>1</sup> Herbal remedies containing aristolochic acid. *Note—this nomination was previously identified as "Aristolochia-Related Herbal Remedies".	Several <i>Aristolochia</i> species (notably <i>A. contorta</i> , <i>A. debilis</i> , <i>A. fangchi</i> and <i>A. manshuriensis</i> ) have been used in traditional Chinese medicine as antirheumatics, as diuretics, in the treatment of edema, and for other conditions such as hemorrhoids, coughs, and asthma.	NIEHS .....	Herbal remedies containing the plant genus <i>Aristolochia</i> : IARC <sup>2</sup> finding of sufficient evidence of carcinogenicity in humans (IARC Monograph Vol. 82, 2002).	Review for possible listing in 12th RoC.



## STATUS OF NOMINATIONS TO BE REVIEWED FOR THE REPORT ON CARCINOGENS—Continued

Nomination/CAS No.	Primary uses or exposures	Nominator	Basis for nomination	Status
Aristolochic Acid .....	Aristolochic acid, the principle extract from Aristolochia, is a mixture of nitrophenanthrene carboxylic acids.	NIEHS .....	Naturally occurring mixtures of aristolochic acids: IARC <sup>2</sup> finding of sufficient evidence of carcinogenicity in animals and limited evidence in humans (IARC Monograph Vol. 82, 2002).	Review for possible listing in 12th RoC.
Asphalt fumes .....	Asphalt is a petroleum product used in paving and roofing operations. Asphalt fumes are a cloud of small particles generated after volatilization of asphalt aggregates.	Private Individual .....	Human epidemiological studies have reported an increased risk of lung cancer among workers exposed to asphalt fumes and asphalt fumes caused skin tumors in experimental animals. Additionally, known human carcinogens (polycyclic aromatic hydrocarbons or PAHs) have been found in asphalt fumes.	Defer review of nomination until the 13th RoC.
Atrazine (192–24–9) .....	Atrazine is an herbicide used to control grass and broad-leaved weeds. Atrazine has been detected at levels that exceeded or approached the maximum contaminant level (MCL) for atrazine in 200 community surface drinking water systems.	NIEHS .....	IARC <sup>2</sup> finding of sufficient evidence of carcinogenicity in animals (IARC Monograph Vol. 73, 1999).	Defer review of nomination until the 13th RoC.
Benzofuran (271–89–6) .....	Benzofuran is produced by isolation from coal-tar oils. Benzofuran is used in the manufacture of coumarone-indene resins, which harden when heated and are used to make floor tiles and other products.	NIEHS .....	Results of a NTP bioassay (NTP Technical Report 370, 1989) <sup>3</sup> , which reported clear evidence of carcinogenicity in male and female mice and some evidence of carcinogenicity in female rats.	Defer review of nomination until the 13th RoC.
Captafol (2425–06–01) .....	Captafol is a fungicide that has been widely used since 1961 for the control of fungal diseases in fruits, vegetables, and some other plants. Use of captafol in the United States was banned in 1999.	NIEHS .....	IARC <sup>2</sup> finding of sufficient evidence of carcinogenicity in animals (IARC Monograph Vol. 53, 1991). IARC also noted that captafol is positive in many genetic assays including the in-vivo assay for dominant lethal mutation.	Review for possible listing in 12th RoC.
<sup>1</sup> Cobalt-tungsten carbide powders and hard metals. *Note—This nomination was previously identified as “Cobalt/Tungsten-Carbide Hard Metal Manufacturing”.	Cobalt-tungsten carbide hard-metals are manufactured by a process of powder metallurgy from tungsten and carbon (tungsten carbide), and small amounts of other metallic compounds using cobalt as a binder. They are used to make cutting and grinding tools, dies, and wear products for a broad spectrum of industries including oil and gas drilling, and mining.	NIEHS .....	Recent human cancer studies on the hard metal manufacturing industry showing an association between exposure to hard metals (cobalt tungsten-carbide) and lung cancer.	Review for possible listing in 12th RoC.



## STATUS OF NOMINATIONS TO BE REVIEWED FOR THE REPORT ON CARCINOGENS—Continued

Nomination/CAS No.	Primary uses or exposures	Nominator	Basis for nomination	Status
Di (2-ethylhexyl) phthalate (DEHP) (117–81–7).	DEHP is mainly used as a plasticizer in polyvinyl chloride (PVC) resins for fabricating flexible vinyl products. PVC resins have been used to manufacture toys, dolls, vinyl upholstery, tablecloths, and many other products.	Private Individual .....	Currently listed in the RoC as reasonably anticipated to be a human carcinogen. IARC <sup>2</sup> reclassification as not classifiable as to its carcinogenicity to humans (Group 3) (IARC Monograph Vol. 77, 2000). IARC stated that there was sufficient evidence for the carcinogenicity in experimental animals; however, the mechanism for liver tumor involves peroxisome proliferation that is not relevant to humans.	Review for possible removal of listing in 12th RoC.
Etoposide in combination with cisplatin and bleomycin.	Etoposide in combination with cisplatin and bleomycin is used to treat testicular germ cell cancers.	NIEHS .....	IARC <sup>2</sup> finding of sufficient evidence of carcinogenicity in humans (IARC Monograph Vol. 76, 2000).	Review for possible listing in 12th RoC.
Etoposide (33419–42–0) ...	Etoposide is a DNA topoisomerase II inhibitor used in chemotherapy for non-Hodgkin's lymphoma, small-cell lung cancer, testicular cancer, lymphomas, and a variety of childhood malignancies.	NIEHS .....	IARC <sup>2</sup> finding of limited evidence of carcinogenicity in humans (IARC Monograph Vol. 76, 2000).	Review for possible listing in 12th RoC.
Formaldehyde (50–00–0) ..	Formaldehyde is primarily used in the production of resins that are used in the production of many different products including plastics, adhesives and binders for wood products, pulp and paper, synthetic fibers, and in textile finishing. It is also used as a disinfectant and preservative and as an intermediate for many industrial chemicals.	NIEHS .....	Formaldehyde (gas) is currently listed in the RoC as reasonably anticipated to be a human carcinogen. Nominated for reconsideration based on the 2004 IACR <sup>2</sup> review, which concluded that there was sufficient evidence for the carcinogenicity of formaldehyde in humans (IARC Monograph Vol. 88, 2004).	Review for possible reclassification of listing status in 12th RoC.



## STATUS OF NOMINATIONS TO BE REVIEWED FOR THE REPORT ON CARCINOGENS—Continued

Nomination/CAS No.	Primary uses or exposures	Nominator	Basis for nomination	Status
<sup>1</sup> Certain Glass Wool Fibers. *Note—This nomination was previously identified as “Glass wool (respirable size): Two nominations: (1) Insulation glass wool fibers, and (2) Special purpose glass fibers”.	Glass wool fibers, which are a type of synthetic vitreous fibers, are an inorganic fibrous material manufactured primarily from glass and processed inorganic oxides. The composition of these fibers may vary substantially because of differences in end-use, manufacturing requirements, and biopersistence considerations. The major uses of glass wool are in thermal, electrical, and acoustical insulation, weather-proofing, and filtration media. Some glass wool fibers (special purpose fibers) are used for high-efficiency air filtration media, and acid battery separators.	North American Insulation Manufacturers Association nominated glass wool (respirable size) for delisting. NIEHS recommended that the nomination be defined as “certain glass wool fibers” because of the considerable differences in the composition of glass wool fibers.	Glass wool (respirable size) is currently listed in the RoC as reasonably anticipated to be a human carcinogen. Insulation glass wool: IARC <sup>2</sup> finding of limited evidence of carcinogenicity in animals and evaluation as not classifiable as to its carcinogenicity to humans (Group 3) (IARC Monograph Vol. 81, 2002). Special-purpose glass fibers: IARC <sup>2</sup> finding of sufficient evidence of carcinogenicity in animals (IARC Monograph Vol. 81, 2002).	Review for possible listing in 12th RoC.
Metalworking Fluids .....	Metal working fluids are complex mixtures that may contain mixtures of oil, emulsifiers, anti-weld agents, corrosion inhibitors, extreme pressure additives, buffers, biocides, and other additives. They are used to cool and lubricate tools and working surfaces in a variety of industrial machining and grinding operations.	NIEHS .....	Recent human cancer studies of metal working fluids that show an association between exposure to these materials and cancer at several tissue sites.	Review for possible listing in 12th RoC.
ortho-Nitrotoluene (88–72–2).	ortho-Nitrotoluene is used to synthesize agricultural and rubber chemicals, azo and sulfur dyes, and dyes for cotton, wool, silk, leather, and paper.	NIEHS .....	Results of a NTP bioassay (NTP Technical Report 504, 2002) <sup>3</sup> , which reported clear evidence of carcinogenicity in rats and mice.	Review for possible listing in 12th RoC.
Oxazepam (604–75–1) .....	Oxazepam is a benzodiazepine used extensively since the 1960s for the treatment of anxiety and insomnia and in the control of symptoms of alcohol withdrawal.	NIEHS .....	Results of a NTP bioassay (NTP Technical Report 443, 1993) <sup>3</sup> , which reported clear evidence of carcinogenicity in male and female mice.	Defer review of nomination until the 13th RoC.
Riddelliine (23246–96–0) ..	Riddelliine is found in class of plants growing in western United States. Cattle, horses, and sheep ingest these toxic plants. Residues have been found in milk and honey.	NIEHS .....	Results of a NTP bioassay (NTP Technical Report 508, 2003) <sup>3</sup> , which reported clear evidence of carcinogenicity in male and female rats and mice.	Review for possible listing in 12th RoC.
Styrene (100–42–5) .....	Styrene is used in the production of polystyrene, acrylonitrile-butadiene-styrene resins, styrene-butadiene rubbers and latexes, and unsaturated polystyrene resins.	Private Individual .....	IARC <sup>2</sup> finding of limited evidence of carcinogenicity in animals and limited evidence of carcinogenicity in humans (IARC Monograph Vol. 82, 2002).	Review for possible listing in 12th RoC.



## STATUS OF NOMINATIONS TO BE REVIEWED FOR THE REPORT ON CARCINOGENS—Continued

Nomination/CAS No.	Primary uses or exposures	Nominator	Basis for nomination	Status
Talc (Two nominations) ..... (1) Cosmetic talc ..... (2) Occupational exposure to talc.	Talc occurs in various geological settings around the world. Exposure to general population occurs through use of products such as cosmetics. Occupational exposure occurs during mining, milling, and processing.	NIEHS .....	The NTP deferred consideration of listing talc (asbestiform and non-asbestiform talc) in the 10th RoC because its 2000 review of talc found that there has been considerable confusion over the mineral nature and consequences of exposure to talc, both containing asbestiform fibers and not containing asbestiform fibers. It has become evident that the literature on both forms of talc, with a few exceptions, provides an inadequate characterization of the actual materials under study to enable one to reach definitive conclusions concerning the specific substances responsible for the range of adverse health outcomes reported.	Withdrawn from review.
Teniposide (29767–20–2)	Teniposide is a DNA topoisomerase II inhibitors used mainly in the treatment of adult and childhood leukemia.	NIEHS .....	IARC <sup>2</sup> finding of limited evidence of carcinogenicity in humans (IARC Monograph Vol. 76, 2000).	Review for possible listing in 12th RoC.
Vinyl Mono-Halides as a class.	Vinyl halides are used in the production of polymers and copolymers. Vinyl bromide is mainly used in polymers as a flame retardant and in the production of monoacrylic fibers for carpet-backing materials. Vinyl chloride is used to produce polyvinyl chloride and copolymers. Vinyl fluoride is used in the production of polyvinyl fluoride, which when laminated with aluminum, steel and other materials, is used as a protective surface for the exteriors of residential and commercial buildings.	NIEHS .....	Vinyl fluoride and vinyl bromide are currently listed in the RoC as reasonably anticipated to be a human carcinogen and vinyl chloride is currently listed in the RoC as a known to be a human carcinogen. Vinyl mono-halides: Structural similarities and common mechanisms of tumor formation.	Defer review of nomination until the 13th RoC.

<sup>1</sup> Nomination has been redefined based on public comments received from earlier **Federal Register** notices and/or review of the literature.<sup>2</sup> International Agency for Research on Cancer (IARC). IARC Monographs are available from <http://monographs.iarc.fr/>.<sup>3</sup> NTP Technical Reports are available at <http://ntp.niehs.nih.gov/> see "NTP Study Reports."



[FR Doc. 05-20729 Filed 10-17-05; 8:45 am]  
BILLING CODE 4140-01-P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[FEMA-1605-DR]

#### Alabama; Amendment No. 7 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Alabama (FEMA-1605-DR), dated August 29, 2005, and related determinations.

**EFFECTIVE DATE:** October 5, 2005.

**FOR FURTHER INFORMATION CONTACT:** Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-2705.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Alabama is hereby amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of August 29, 2005: Marengo County for Individual Assistance (already designated for Public Assistance.)

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

**R. David Paulison,**

*Acting Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.*

[FR Doc. 05-20770 Filed 10-17-05; 8:45 am]

BILLING CODE 9110-10-P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[FEMA-1603-DR]

#### Louisiana; Amendment No. 4 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA-1603-DR), dated August 29, 2005, and related determinations.

**EFFECTIVE DATE:** October 7, 2005.

**FOR FURTHER INFORMATION CONTACT:** Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-2705.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Louisiana is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of August 29, 2005:

All parishes in the State of Louisiana are eligible to apply for assistance under the Hazard Mitigation Grant Program. (The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

**R. David Paulison,**

*Acting Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.*

[FR Doc. 05-20769 Filed 10-17-05; 8:45 am]

BILLING CODE 9110-10-P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[FEMA-1607-DR]

#### Louisiana; Amendment No. 7 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA-1607-DR), dated September 24, 2005, and related determinations.

**EFFECTIVE DATE:** October 7, 2005.

**FOR FURTHER INFORMATION CONTACT:** Magda Ruiz, Recovery Division, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-2705.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Louisiana is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of September 24, 2005:

Evangeline, Sabine, St. Landry, and Vernon Parishes for Public Assistance [Categories C-G] (already designated for Individual Assistance and debris removal and emergency protective measures [Categories A and B] under the Public Assistance program, including direct Federal assistance.)

De Soto, Natchitoches, and Rapides Parishes for Public Assistance [Categories C-G] (already designated for debris removal and emergency protective measures [Categories A and B] under the Public Assistance program, including direct Federal assistance.)

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund Program; 97.032, Crisis Counseling; 97.033, Disaster Legal Services Program; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance; 97.048, Individuals and Households Housing; 97.049, Individuals and Households Disaster Housing Operations; 97.050 Individuals and Households Program—Other Needs, 97.036, Public Assistance Grants; 97.039, Hazard Mitigation Grant Program.)

**R. David Paulison,**

*Acting Under Secretary, Emergency Preparedness and Response, Department of Homeland Security.*

[FR Doc. 05-20773 Filed 10-17-05; 8:45 am]

BILLING CODE 9110-10-P



# Exhibit 153



Methodology

Open Access

## Trend tests for the evaluation of exposure-response relationships in epidemiological exposure studies

Ludwig A Hothorn<sup>\*1</sup>, Michael Vaeth<sup>2</sup> and Torsten Hothorn<sup>3</sup>

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### Abstract

One possibility for the statistical evaluation of trends in epidemiological exposure studies is the use of a trend test for data organized in a  $2 \times k$  contingency table. Commonly, the exposure data are naturally grouped or continuous exposure data are appropriately categorized. The trend test should be sensitive to any shape of the exposure-response relationship. Commonly, a global trend test only determines whether there is a trend or not. Once a trend is seen it is important to identify the likely shape of the exposure-response relationship. This paper introduces a best contrast approach and an alternative approach based on order-restricted information criteria for the model selection of a particular exposure-response relationship. For the simple change point alternative  $H_1: \pi_1 = \dots = \pi_q < \pi_{q+1} = \dots = \pi_k$  an appropriate approach for the identification of a global trend as well as for the most likely shape of that exposure-response relationship is characterized by simulation and demonstrated for real data examples. Power and simultaneous confidence intervals can be estimated as well. If the conditions are fulfilled to transform the exposure-response data into a  $2 \times k$  table, a simple approach for identification of a global trend and its elementary shape is available for epidemiologists.

### Introduction

Statistical trend analysis is an important component of epidemiological exposure studies. Here, "trend" simply means the demonstration of any monotone relationship between the response rate and the continuous exposure. For example, the association between all major types of childhood cancer and exposure to magnetic fields from high voltage installations was analyzed by Lausen et al. [1] using the data shown in Table 1, where the original continuous exposure data (Olsen et al., [2]) were categorized.

Although this example is seriously unbalanced, real epidemiological exposure studies with many unexposed or low-

exposure cases but few high-exposure cases can be found. The appropriate evaluation of such epidemiological exposure studies is a statistical challenge. Many similar examples can be found in the literature, e.g. a case-control study for respiratory cancer possibly caused by long-term exposure to coke oven emissions [3].

In exposure studies, an unexposed group,  $E_1$ , is commonly compared with several exposure groups,  $E_2, \dots, E_k$ . The outcome of the study is the number of cases suffering from the disease being investigated, such as a specific tumor, and the number of observations without the disease (controls), i.e. the risk of disease in each category of



**Table 1: Child cancer and magnetic fields**

Exposure/ $\mu$ Tesla	$j$	$n_{\text{cancer}}$	$n_{\text{no cancer}}$	$n_j$	$\hat{p}_j$	$RR_{j1}$
0-0.05	1	1698	4759	6457	0.263	-
0.051-0.101	2	0	9	9	0	0.000
0.101-0.15	3	2	3	5	0.4	1.525
0.151-0.20	4	1	3	4	0.25	0.953
0.201-0.25	5	1	3	4	0.25	0.953
0.251-0.30	6	0	4	4	0	0.000
0.301-0.35	7	0	2	2	0	0.000
0.351-0.85	8	1	0	2	0.5	1.906
0.851-1.6	9	2	0	2	1	3.812
>1.61	10	2	0	2	1	3.812

( $\hat{p}_j$  ... estimated proportion,  $RR_{j1}$  ... relative risk to unexposed)

exposure. One important objective in exposure epidemiology is causation; the demonstration of a global exposure-response relationship represents one of the causation criteria, according to Hill [4]. A global trend test leads to identification of a trend, whereas model selection allows inference of the likelihood of a particular elementary model.

The sampling strategy of epidemiological exposure studies is either a cohort study, in which a  $2 \times k$  contingency table represents the data, or a case-control study, in which two multinomial distributions are compared. However, the likelihood ratio test of identical multinomials against the elementary odds ratios alternative, for a sufficient total number of observations, is equivalent to the comparison of the  $k$  independent binomial proportions against a simple ordered alternative (Agresti and Coull, [5]; Hothorn et al., [6]). Therefore, it is appropriate to evaluate both designs by means of an asymptotic trend test for a  $2 \times k$  contingency table.

Numerous methods, including model-based (e.g. Royston et al., [7]) and test-based approaches (e.g. Dosemeci and Benichou, [8]), are used to analyze exposure-response relationships. A basic problem is that the shape of the exposure-response is unknown a priori and is an outcome of the study. However, the choice of model or test greatly depends on the shape of the exposure-response. Therefore, a broad class of models or tests should be used, but that, in turn, leads to a model selection dilemma. Model selection is an intricate component of statistical problems. Model selection in this case is not the objective, but is only a tool for identifying the correct trend from several possible elementary alternatives. An alternative hypothesis can be decomposed into its underlying elementary alternatives, e.g. the simple order alternative  $H_1: \pi_1 \leq \pi_2 \leq \pi_3$  can be decomposed into the three elementary hypotheses  $H_1^1$

:  $\pi_1 = \pi_2 < \pi_3$ ,  $H_1^2: \pi_1 < \pi_2 = \pi_3$ ,  $H_1^3: \pi_1 < \pi_2 < \pi_3$ .

The  $p$ -value, a commonly used outcome of a trend test, is frequently insufficient for epidemiological studies. Information concerning the shape of the exposure-response and/or a measure of the magnitude of the effect, such as relative risks or odds ratios, is desirable for a significant trend. Thus, the level of the false positive decision rate ( $\alpha$ ) should be controlled. In addition, an approach with a minimum false negative decision rate ( $\beta$ ) (respective maximum power  $\pi = 1 - \beta$ ) for the global test decision and a maximum correct decision rate for the selected model should be identified. The correct classification rate, the proportion of correctly identified elementary alternatives, is used as a major performance measure later on.

The exposure in case-control studies is frequently measured on a continuous scale. Categorization at pre-selected cut-off points of a small number of ordered categories is common; for example, four categories of trihalomethane exposure (Jones et al., [9]), or three categories of lifetime dose of hair dye (Benavente et al., [10]). Inappropriately chosen cut-off points dramatically reduce the power of the trend test (Greenland, [11]). Some exposures are naturally grouped, for example 2-3 cups of coffee per day, by the impreciseness of the definitions, such as "cup" and "coffee" (Ascherio et al., [12]). An example of ordinal definition of the exposure is given in a case-control study of Norwegian nickel refinery workers (Grimsrud et al., [13]). The exposure-related associations between smoking-adjusted lung cancer rates and cumulative exposure to different forms of nickel used the categories "low," "medium," and "high."

The best approach, in terms of both power and interpretation, occurs when a single cut-off point exists and is known a priori, resulting in a two-sample test "above" vs. "below" the cut-off point. This is because an odds ratio and its one-sided confidence interval can be estimated. The trend test approach discussed here is designed for naturally grouped exposure with a single change point. For continuous exposure models a continuous covariate can be used. However, the choice of an appropriate model – such as linear, logistic, or other – remains open and model selection influences the inference.

In this paper, a trend test for the comparison of  $k$  ordered binomial proportions using a change point alternative is presented. Either a single change point is directly of interest or the change point alternative is pivotal, i.e. many other elementary monotone alternatives can be generated from it. The concept of multiple contrasts is used because of the simplicity and the availability of the distribution under the alternative. After a significant trend test, information is provided that determines which contrast was the "best," and therefore, which exposure-response shape describes the data most accurately. Alternatively, an information criterion-based approach for the likelihood ratio



test under monotone order-restriction according to Anraku [14] is examined.

Therefore, the primary objective of this paper is not just describing the exposure-response relationship but also identifying the most likely elementary exposure-response model with a control of the false model classification rate.

## Analysis

### Global tests on exposure-response relationships

The number of diseased and healthy persons for each exposure group,  $E_j$ , are organized in the following  $2 \times k$  table, where Index 1 denotes the group without exposure.

The estimator for the proportions per exposure group is  $p_j = n_{j1}/n_j$ ,  $j = 1, \dots, k$ , the total is  $p = n_{.1}/n_{..}$ , and the expected values for the proportions are denoted as  $\pi_j$ . The hypotheses system for a monotone order is:

$$H_0: \pi_1 = \pi_2 = \dots = \pi_k \text{ against}$$

$$H_1: \pi_1 \leq \pi_2 \leq \dots \leq \pi_k \text{ with at least one strict inequality.}$$

For simplicity, assume increasing effects with increased exposure; analogously, a directional decision for a decrease is possible.

There are an extensive number of publications concerning order-restricted tests, including the analysis of  $2 \times k$  contingency tables (e.g. Agresti and Coull, [5]; Leuraud and Benichou, [15]). However, no uniformly powerful trend test exists for all possible alternative shapes. The possible shapes can be seen as different equality-inequality patterns of  $H_1$ . This can be seen for an extreme convex shape  $\{0, 0, 0, \pi\}$ . Clearly, the "Helmert's contrast" is most powerful because of the optimal pooling of all the lower exposures and the comparison with the high exposure:  $p_4 - (p_1 + p_2 + p_3)/3$ . However, power for Helmert's contrast is greatly reduced for the extreme concave shape  $\{0, \pi, \pi, \pi\}$ . The shape of the exposure-response relationship is unknown a priori. Irrespective of numerous recent alternative proposals, the likelihood ratio test represents an appropriate solution for this situation. This test is numerically complicated, particularly concerning its distribution

under the alternative, which is needed for power/sample size calculations (Robertson et al., [16]). The multiple contrast test according to Bretz and Hothorn [17] approximates its power and is simpler. There are  $2^k - 1$  different shapes for  $k$  exposure groups, and for each shape a contrast with a minimum false negative rate ( $\beta$ ) can be defined. The idea is to select the best contrast, which is sensitive for a certain shape. The best contrast is simply tested by a maximum test. Because the proportions  $p_j$  are asymptotically normally distributed, their linear combination (denoted as contrast)  $\sum_{j=1}^k c_j p_j$  is also normally distributed, and therefore, the single contrast test statistic

$$t_{\text{SingleC}} = \frac{\sum_{j=1}^k c_j p_j}{\sqrt{p(1-p) \sum_{j=1}^k c_j^2 / n_j}} \text{ is asymptotically normally}$$

distributed, where  $\sum_j c_j = 0$  guarantees a level  $\alpha$  test under the null hypothesis. Different variance estimators can be used, but to keep the problem simple, the commonly used pooled estimator  $p$  is used here. Asymptotic test versions are used throughout. The contrast coefficients,  $c_j$ , are specific for each contrast test; for example the Helmert's contrast [ $c_i = -1$ ;  $j = 1, \dots, k-1$  and  $c_k = k$ ]. A multiple contrast test is the maximum of  $s$  pre-defined single contrast tests

$$t_{\text{MultipleC}} = \max_{i \in \{1, \dots, s\}} (t_{\text{SingleC}}(c_i)), \quad i = 1, \dots, s \text{ where } c_i = (c_{i1}, \dots, c_{ik}) \text{ is a } k \text{ vector of contrasts. Under the null hypotheses, the joint distribution of the linear contrast tests } t_{\text{SingleC}}(c_i) \text{ } i = 1, \dots, s \text{ is an } s\text{-variate normal distribution with a zero vector of means and a non-product-moment correlation matrix. The correlation between two arbitrary contrasts, } \mathbf{a} = (a_1, \dots, a_k) \text{ and } \mathbf{b} = (b_1, \dots, b_k), \text{ is}$$

$$\rho_{\mathbf{a}, \mathbf{b}} = \frac{\sum_{j=1}^k a_j b_j \frac{p_j(1-p_j)}{n_j}}{\sqrt{\left( \sum_{j=1}^k a_j^2 \frac{p_j(1-p_j)}{n_j} \right) \left( \sum_{j=1}^k b_j^2 \frac{p_j(1-p_j)}{n_j} \right)}}$$

This so-called isotonic contrast approach, based on  $s = 7$  contrasts, for the balanced design with four exposure groups is demonstrated in Table 3.

However, the correct classification rates for the most likely elementary alternative (shape of the exposure-response) were found to be unsatisfactory for isotonic contrasts (Hothorn et al., [6]). Therefore, a special case of order-

**Table 2: Principle of 2 by k tables for epidemiological exposure studies**

	$E_1$	....	$E_k$	Total
Disease	$n_{11}$	...	$n_{k1}$	$n_{.1}$
No disease	$n_{10}$	...	$n_{k0}$	$n_{.0}$
Sample size	$n_{1.}$	...	$n_{k.}$	$n_{..}$



restricted inference is considered for step shapes only and denoted as a change point alternative (Hirotzu and Marumo, [18]). Two situations should be considered: i) threshold level studies assuming that an exposure-response reveals a single change point, which can be characterized by a lower part, an upper part, and an abrupt change between both; and ii) exposure-response studies with continuous exposure data where the change point alternative is a special and substantial component of the all-pattern alternative, which can simplify the evaluation. In some epidemiological problems this question arises. An example of a threshold level study is a diabetes study (Pastor-Barriuso et al., [19]) with the relationship between 2-hour plasma glucose and mortality, where the following questions were formulated: i) Does a certain glucose level exist that markedly increases the mortality risk? ii) Can this change point be estimated? Proposals in the literature are directed only at proof of the existence of such a change point. However, epidemiologists not only want to know that such a change exists, but also where this change is located. Here it is demonstrated that the estimation of the change point  $q$  is characterized by its correct classification rate by means of multiple contrast tests, that is, in a testing framework. The hypotheses system for a change from  $q$  to  $q+1$  is:

$$H_0: \pi_1 = \pi_2 = \dots = \pi_k$$

$$H_1: \pi_1 = \dots = \pi_q < \pi_{q+1} = \dots = \pi_k \quad q \in (1, \dots, k-1)$$

The above hypotheses system can be tested by multiple step contrasts. Exactly  $(k-1)$  step contrasts are appropriate for testing the above hypothesis:

$$\begin{pmatrix} -k, & 1, & 1, & \dots & 1 \\ -(k-1), & -(k-1), & 2, & \dots & 2 \\ \dots & \dots & \dots & \dots & \dots \\ -1, & -1, & -1, & \dots & k \end{pmatrix}$$

**Table 3: Contrast coefficients for the balanced design with four exposures groups**

Type of contrasts	No. of contrasts	Alternative	Contrast $c_j$
Isotonic	$2^{k-1}$	$\pi_1 < \pi_2 = \pi_3 = \pi_4$	$\{-3 \mid 1 \mid 1\}$
		$\pi_1 = \pi_2 < \pi_3 = \pi_4$	$\{-1 \mid -1 \mid 1\}$
		$\pi_1 = \pi_2 = \pi_3 < \pi_4$	$\{-1 \mid -1 \mid -1 \mid 3\}$
		$\pi_1 < \pi_2 < \pi_3 < \pi_4$	$\{-3 \mid -1 \mid 1\}$
		$\pi_1 = \pi_2 < \pi_3 < \pi_4$	$\{-1 \mid -1 \mid 0 \mid 2\}$
		$\pi_1 < \pi_2 = \pi_3 < \pi_4$	$\{-1 \mid 0 \mid 0 \mid 1\}$
Change point	$k-1$	$\pi_1 < \pi_2 < \pi_3 = \pi_4$	$\{-2 \mid 0 \mid 1\}$
		$\pi_1 < \pi_2 = \pi_3 = \pi_4$	$\{-3 \mid 1 \mid 1\}$
		$\pi_1 = \pi_2 < \pi_3 = \pi_4$	$\{-1 \mid -1 \mid 1\}$
		$\pi_1 = \pi_2 = \pi_3 < \pi_4$	$\{-1 \mid -1 \mid -1 \mid 3\}$
Up/down	2	$\pi_1 < \pi_2 = \pi_3 = \pi_4$	$\{-3 \mid 1 \mid 1\}$
		$\pi_1 = \pi_2 = \pi_3 < \pi_4$	$\{-1 \mid -1 \mid -1 \mid 3\}$
Single (linear)	1	$\pi_1 < \pi_2 < \pi_3 < \pi_4$	$\{-3 \mid -1 \mid 1 \mid 3\}$

Exactly three possible change points,  $q$ , exist for the simple design with one unexposed and three exposure groups. Exactly one contrast is power-optimal for the balanced design of each change point:

$q$	$c_1$	$c_2$	$c_3$	$c_4$
1	(-3	1	1	1)
2	(-2	-2	2	2)
3	(-1	-1	-1	3)

"Power-optimal" simply means the maximum test statistics because the  $t_{SingleC}^i$  is normally distributed, and therefore, standardized. The  $t_{MultipleC}$  is  $q$ -variate normally distributed. The contrast coefficients,  $c$ , for  $q$  contrasts are defined for the general unbalanced design (Hirotzu et al., [20]):

$$c_{qj} = \begin{cases} -n_j / \sum_{l=1}^j n_l & \text{if } j = 1, \dots, q \\ n_j / \sum_{l=j}^k n_l & \text{if } j = q+1, \dots, k \end{cases}$$

These step contrasts reveal a nice ability to transform the  $k$ -sample problem into an unbalanced two-sample problem, which can be used later for estimation of the unadjusted relative risk (or odds ratio) "above/below" the change point. Moreover, the step contrasts belong to a broader class of multiple contrasts. Isotonic contrasts approximate the power of the likelihood ratio test for the monotone ordered hypothesis. The bivariate up/down proposals (Neuhaus and Hothorn, [21]; Stewart and Ruberg, [22]) only use the two extreme contrasts (Table 3). Therefore, the change point alternative represents a compromise for testing trends. It is much less dependent on the power of the shape compared with the frequently used single linear contrast test, although only  $k$  instead of  $2^k - 1$  isotonic contrasts were used. The multiple contrast test (above) is defined for differences of proportions, but can be re-formulated for the relative risk, commonly used in epidemiology (see Appendix A).

It seems that a multiple contrast test may be a different approach to the commonly used logistic model. However, a strong relationship between the multiple contrast test and the score test in a logistic model exists, which allows the correction for additional confounders (Hothorn et al., [6]).

#### Identification of the exposure-response shape

The trend tests distinguish only globally between the null hypothesis and alternative hypotheses, based on the



asymptotic distribution of the test statistics under the null hypothesis. That is, either a trend exists or it does not. However, the alternative hypothesis is not unique. For example, the following three hypotheses are possible for the change point alternative for a design with one unexposed and three exposure groups:

$$H_1^1 : \pi_1 < \pi_2 = \pi_3 = \pi_4, H_1^2 : \pi_1 = \pi_2 < \pi_3 = \pi_4, H_1^3 : \pi_1 = \pi_2 = \pi_3 < \pi_4$$

However, the global trend tests provide no answer as to which particular alternative exists. Two different approaches can be used to answer this question: i) the best contrast approach; and ii) a model selection approach based on the information criterion for order restriction. This paper explores the identification of one of the possible  $k - 1$  elementary alternatives; that is, a classification into  $H_1^1, \dots, H_1^{k-1}$ . Consequently, the correct classification rate, or the proportion of correctly identified elementary alternatives, is used as a performance measure later on.

The global test decision for the multiple contrast approach is based on the maximum of all included single contrasts  $t_{MultipleC} = \max_{i \in \{1, \dots, s\}} (t_{SingleC}(c_i))$ ,  $i = 1, \dots, s$ , where each single contrast is power optimal for a particular type of alternative (Table 3). Therefore, this maximum contrast approach can be used as an estimator for the exposure-response shape, where the classification is performed after a significant trend test for control  $\alpha$ . For example, two alternatives are possible for a design with three exposure groups:  $H_1^1 : \pi_1 = \pi_2 < \pi_3$  or  $H_1^2 : \pi_1 < \pi_2 = \pi_3$ . Assume that the number of diseased cases,  $n_{11}, \dots, n_{k1}$ , is drawn from  $k$  binomial random variables with parameters  $\pi_j$  and  $n_j$ . A possible exposure-response is described by a contrast vector,  $c = (c_1, \dots, c_k)$ . The problem is to estimate the underlying exposure-response relationship when  $s$  contrast vectors are given. A simple estimator is the function  $\Psi : (n_{11}, \dots, n_{k1}) \rightarrow \{1, \dots, s\}$  which can be derived from the associated contrast test, i.e.  $\psi_1 = \psi(n_{11}, \dots, n_{k1}) = \arg \max_{i \in \{1, \dots, s\}} |t_{SingleC}(c_i)|$ . Then explore variability of the simple estimator,  $\Psi_1$ . How likely is each of the  $s$  possible values under the observed data? This question can be addressed via the parametric bootstrap. Repeated realizations from  $k$  binomial distributions with sample sizes  $n_j$  and the estimated success parameter  $p_j = n_{j1}/n_j$  for  $j = 1, \dots, k$  are drawn.

- Draw  $B$  bootstrap samples  $n_{11}^{*b}, \dots, n_{k1}^{*b}, n_{j1}^{*b} \sim B(n_j, p_j)$ ,  $b = 1, \dots, B$

- Compute  $\psi_1^b = \psi_1(n_{11}^{*b}, \dots, n_{k1}^{*b})$

- Compute the relative frequency of each possible value from  $1, \dots, s$

This is a measure for the variance of the estimator. Under special circumstances, an improved estimator can be computed by a majority voting according to Breiman [23] over  $\psi_1^b : \psi_2 = \arg \max_{i \in \{1, \dots, s\}} \sum_b I(\psi_1^b = i)$ , where  $I$  denotes the indicator function. This approach is designated the "parametric bootstrap best contrast" approach.

The model selection approach, based on the information criterion for order-restriction of normally distributed variables according to Anraku [14], can be modified for proportions and the change point alternative. The AIC criterion for the unrestricted maximum likelihood estimator  $\hat{\theta} : AIC(\hat{\theta}) = l(\hat{\theta}) - p$ : (with  $l(\hat{\theta}) = \log\text{-likelihood}$ ,  $p = \text{dimension of } \theta$ ) was modified for order-restricted maximum likelihood estimators:  $ORIC(\tilde{\theta}) = l(\tilde{\theta}) - \text{penalty}(k, n_i)$ . The penalty term is calculated for each model using the level of probabilities under an order-restriction. The explicit formulas for a design with three exposure groups, such as the null-model  $M_0$  and the two change point models  $M_1$  and  $M_2$ , are given in Appendix B. The ORIC-approach represents a model estimation approach, where model  $M_0 \{H_0 : \pi_1 = \pi_2 = \pi_3\}$ , model  $M_1 \{H_{M_1} : \pi_1 = \pi_2 < \pi_3\}$ , or model  $M_2 \{H_{M_2} : \pi_1 = \pi_2 < \pi_3\}$  will be estimated as a "best fitted" model.

### Simulation study

The simulation study is structured in two parts: i) empirical comparison between the best-contrast approach and the ORIC approach for a design with three groups; and ii) investigation of the best contrast approach for more general designs. Fifty thousand pseudo-random  $2 \times k$  tables ( $k$  ranging from 3 to 7) were generated and 10,000 bootstrap samples were drawn. Two criteria are used, the correct classification rate – the empirical decision rate for the correct model – and the power.

#### Part I

The correct classification rates for the ORIC approach, ORIC ( $M_0, M_1, M_2$ ), and the parametric bootstrap best



contrast approach,  $\text{Max}(H^1, H^2)$ , were compared for a design with three exposure groups (in Table 4) for the change point alternatives with different unexposed rates,  $\pi_1$ . From the first row in Table 4, where no differences between the proportions were investigated, the main difference between both approaches becomes clear. The ORIC approach, as an estimation approach, did not control for  $\alpha$ . Only in 76% of the cases, not 95%, was  $M_0$  selected under the null hypothesis. On the other hand, the best contrast test approach does control for  $\alpha$ . Both approaches reveal high correct classification rates, greater than 90%, as long as the power is sufficient: either small unexposed rates,  $\pi_1$ , or large non-centrality parameters  $\Delta$  (Table I in Appendix C (available as additional file 1) and larger sample sizes in Table II in Appendix C). This behavior is similar to the power of trend tests of proportions (Bretz and Hothorn, [17]). Due to the fact that the correct classification rates of the best contrast approach are similar or superior to those of the ORIC approach with decreasing  $\pi_1$ , increasing  $\Delta$ , and  $n_j$ , the best contrast approach is recommended because of its simplicity and generalizability for use within the generalized linear model.

#### Part II

For one selected change point alternative  $\{\pi_1, \pi_1, \pi_1, \pi_1, \pi_1 + \Delta\}$  the best contrast approach was investigated for the different dimensions  $k$ , different unexposed rates  $\pi_1$ , and several non-centrality parameters  $\Delta$ , shown in Table 5. With an increasing number of exposure groups, a slight decrease of the correct classification rate occurs where the power is slightly increasing. With a decreasing sample size, a slight decrease of the correct classification rate occurs where the power is substantially decreasing. The well-known decrease of sensitivity with an increasing unexposed rate from  $2 \times 2$  table analysis holds true for power and, less markedly, for the correct classification

rate. The effect size (non-centrality  $\Delta$ ) has much less impact on the correct classification rate compared with its well-known impact on power.

Table 6 demonstrates the decreasing correct classification rate for change points  $q \ll k$ . More important, from an epidemiological point of view, are the asymmetrical cumulative false classification rates. False classification is primarily from an overestimation instead of an underestimation of the true change point, that is, it is very unlikely to mistake a lower change point for the true one.

#### Extreme unbalanced exposure data

Particularly for environmental studies, much of the data is for unexposed and low-to-medium exposures; only rarely does data for high exposure exist. This is quite fortunate from an ethical point of view. However, this results in extremely unbalanced  $2 \times k$  tables and the statistical outcome depends on the rare, high-level exposure data. In a case-control study for respiratory cancer possibly caused by long-term exposure to coke oven emissions, the sample size was 10,198 in the unexposed group, but only 487 were in the highest exposure group (Costantino et al., [3]). A more extreme example was the study evaluating the connection between childhood cancer and magnetic fields from high voltage installations. The sample size was 2 in the highest exposure group, but 6,457 in the unexposed group (Table 1). The power decreases greatly for extremely unbalanced designs and accordingly the correct classification rate also decreases. If the total sample size is increased to achieve the same power, then the correct classification would be of the same magnitude as the balanced case, see Table 7. The identification of a trend in such a highly unbalanced design is complicated. A significant trend may depend on only these few cases, and the size and power of unbalanced designs differ greatly from those in balanced designs. In unbalanced designs with smaller change points, the correct classification rate increases if the resulting two-sample test is less unbalanced (as a result of the related step contrast). A change point at a high exposure that is based on rare data is very vague, however it becomes more stable when medium-to-high exposure from additional data are obtained.

Unbalanced designs, where the smallest sample size occurs in the informative groups (large change point  $s$ ), reveal a clearly reduced classification rate. However, that decrease, compared with the balanced design, is much weaker than the related power loss. A further reduction occurs for the "in-between" change points as long as the sample size of the pooled informative groups is still smaller than the lower exposure groups. A further substantial increase of the sample size for the unexposed group had almost no influence on the classification rate.

**Table 4: Correct classification rates for several spontaneous rates  $\pi_0$**

$\pi_j$	True Change $q$	ORIC( $M_0, M_1, M_2$ )			Max( $H^1, H^2$ )	
		$M_0$	$M_1$	$M_2$	$H^1$	$H^2$
0.3/0.3/0.3	0	.758	.112	.129	.514	.486
0.1/0.1/0.3	2	.001	<b>.979</b>	.021	<b>.987</b>	.004
0.1/0.3/0.3	1	.001	.020	<b>.980</b>	.030	<b>.961</b>
0.2/0.2/0.4	2	.002	<b>.958</b>	.041	<b>.936</b>	.023
0.2/0.4/0.4	1	.005	.029	<b>.967</b>	.040	<b>.926</b>
0.3/0.3/0.5	2	.006	<b>.940</b>	.054	<b>.906</b>	.034
0.3/0.5/0.5	1	.004	.053	<b>.943</b>	.044	<b>.882</b>
0.4/0.4/0.6	2	.009	<b>.940</b>	.052	<b>.887</b>	.036
0.4/0.6/0.6	1	.009	.053	<b>.940</b>	.039	<b>.885</b>

( $n_j = 100$ ,  $H_1^1 : \pi_0 = \pi_1 < \pi_2$ ,  $H_1^2 : \pi_0 < \pi_1 = \pi_2$ ) (bold indicate correct classification)



**Table 5: Correct classification rates and power for several dimensions, sample sizes, unexposed rates, and non-centralities**

Dimension	k	3	4	5	6	7
Sample size	Correct classif. rate	.992	.987	.977	.971	.971
	Power	.828	.845	.861	.899	.889
	$n_j$	25	50	75	100	125
Unexpos. rate	Correct classif. rate	.809	.973	.978	.987	.989
	Power	.393	.618	.742	.845	.903
	$I_1$	.01	.06	.11	.16	.20
Non-centrality	Correct classif. rate	.987	.903	.817	.767	.766
	Power	.845	.488	.373	.312	.266
	$\Delta$	0.03	0.05	0.07	0.09	0.11
	Correct classif. rate	.953	.973	.985	.994	.998
	Power	.479	.773	.904	.972	.991

Since a sample size of  $n_j = 1$  is possible, in principle, for this approach, the impact of the continuous exposure categorization can be demonstrated quantitatively with respect to power and classification rate. When a single change point exists, the best approach is the categorization below or above this change point. The true alternative is never known a priori when dealing with real data. Therefore, appropriate categorization may be helpful and inappropriate categorization can greatly reduce the sensitivity.

The asymptotic power for the change point alternative is available (Bretz and Hothorn, [17]). Based on an R-code, the power can be calculated for an arbitrary sample size pattern, which shapes the exposure response and dimensions  $k$ . Power estimation for unbalanced designs can be found in [6] whereas a serious power loss can be observed when the sample size in the informative high exposure groups is very small compared with the sample size in the unexposed or low exposure groups.

### Evaluation of the example

The  $p$ -value for the global trend test (change point alternative) and the classification rate of the best contrast approach is determined using an implementation of the proposed procedures in R (R Development Core Team, [24]). The most likely change point,  $q$ , and simultaneous confidence intervals for the related change point contrasts

can be calculated for the  $2 \times k$  contingency table data. A marginal confidence interval can be estimated for each elementary contrast because it represents a linear combination of the proportions  $p_j$ . Simultaneous confidence intervals for the maximum of several contrasts can be estimated using a multivariate normal distribution. A detailed description for the estimation of simultaneous confidence intervals for several multiple contrast tests can be found in [25] where the particular problems for binomial data were described recently [26]. The software is available as the R library *bindosres* as additional file 2. This file can be installed in the private R program via "Install packages from local zip files",

The magnet field cancer data in Table 8 revealed a change point  $q = 8$  with a classification rate of 0.74 ( $p$ -value for a global trend = 0.002). The cumulative false classification of 0.26 is nearly concentrated on  $q = 7$ . The maximum simultaneous lower confidence limit is for the sub-set [10 vs. {1, 2, 3, 4, 5, 6, 7, 8, 9}] and seems to be medically relevant with 0.563, but differs only a little from that of sub-set {10, 9} vs. {1, 2, 3, 4, 5, 6, 7, 8} that is related to the change point. The analysis of the continuous data using maximally selected rank statistics gave a cut-point of 0.45  $\mu$ Tesla<sup>1</sup>. However, above this cut-point only six cancer cases with an exposure of 0.51, 0.73, 1.0, 1.59, 1.66, and 1.72, and two cases without cancer with exposures 0.73 and 0.83  $\mu$  Tesla were available. A careful interpretation is

**Table 6: Asymmetrical cumulative false classification rates**

Alternative	True Change	H <sup>1</sup>	H <sup>2</sup>	H <sup>3</sup>	H <sup>4</sup>	H <sup>5</sup>	Cum. over.	Cum. under.
.01/.01/.01/.01/.01/.07	5	.000	.000	.001	.027	<b>.972</b>	-	0.028
.01/.01/.01/.01/.07/.07	4	.000	.002	.012	<b>.847</b>	.139	0.139	0.014
.01/.01/.01/.07/.07/.07	3	.000	.011	<b>.819</b>	.119	.051	0.17	0.011
.01/.01/.07/.07/.07/.07	2	.004	<b>.809</b>	.117	.038	.032	0.187	0.004
.01/.07/.07/.07/.07/.07	1	<b>.711</b>	.135	.052	.050	.053	0.29	-

( $n_j = 100$ ; bold indicate correct classification)



**Table 7: Correct classification rates for extreme unbalanced designs**

Sample sizes	N	Alternative	Power	Correct classif. rate
200/200/200/200	800	.05/.05/.05/.10	.682	<b>.935</b>
540/200/40/20	800	.05/.05/.05/.10	.251	<b>.758</b>
200/200/200/200	800	.05/.05/.10/.10	.792	<b>.831</b>
540/200/40/20	800	.05/.05/.10/.10	.425	<b>.687</b>
200/200/200/200	800	.05/.10/.10/.10	.603	<b>.783</b>
540/200/40/20	800	.05/.10/.10/.10	.755	<b>.854</b>
400/400/400/400	1600	.05/.05/.05/.10	.915	<b>.971</b>
1340/200/40/20	1600	.05/.05/.05/.10	.266	<b>.749</b>
400/400/400/400	1600	.05/.05/.10/.10	.968	<b>.916</b>
1340/200/40/20	1600	.05/.05/.10/.10	.438	<b>.667</b>
400/400/400/400	1600	.05/.10/.10/.10	.903	<b>.904</b>
1340/200/40/20	1600	.05/.10/.10/.10	.832	<b>.883</b>
9740/200/40/20	10000	.05/.05/.05/.10	.252	<b>.702</b>

recommended: i) the correct classification rate is not high, ii) a high change point was identified, iii) above the change point are only 4 of 6,491 cases, and iv) the spontaneous rate of 0.263 is rather high. More examples and their interpretation can be found in Hothorn et al., [6].

## Conclusion

Trend tests for the analysis of  $2 \times k$  tables using epidemiological exposure data are described to identify the change point alternatives. Not only is the identification of a trend of interest important, but also the information regarding the particular types of alternatives. The best contrast approach for the multiple contrast test is useful for identifying the type of alternative or the change point, whereas a parametric bootstrap is suitable for an assessment of the variability. Both the bootstrapped best contrast and the ORIC approach are appropriate for different dimensions, non-centralities, sample sizes, and the unexposed group rates (due to the asymmetry in binomial testing). The consequences of unbalanced designs – of a large number in the unexposed or low exposure groups and a small number in the high exposure groups – can be calculated

depending on the expected shape. Simultaneous confidence intervals for the change point alternative are also available.

Approaches that test a global trend in epidemiological exposure data and also provide information on the pattern of the exposure-response relationship are rare. The most competitive approach is the fractional polynomials model [7], which is a specific multivariable regression approach.

Most epidemiological studies are characterized not only by the primary exposure factor but also by several covariates, such as gender, age, occupational status, and competing risk characteristics. Therefore, the best contrast approach within the framework of the generalized linear model is recently available [27]. Using the related R library (multcomp), real data can be evaluated using the contrast option "Changepoint" [28].

The suitability of such a simple change point alternative in epidemiological exposure studies should be critically dis-

**Table 8: Child cancer and magnetic fields**

Exposure/ $\mu$ Tesla	$j$	$p_j$	Pattern	Lower confidence limit
0–0.05	1	0.263	{10,9,8,7,6,5,4,3,2} vs. 1	-.716
0.051–0.101	2	0	{10,9,8,7,6,5,4,3} vs. {1,2}	-.410
0.101–0.15	3	0.4	{10,9,8,7,6,5,4} vs. {1,2,3}	-.327
0.151–.20	4	0.25	{10,9,8,7,6,5} vs. {1,2,3,4}	-.246
0.201–0.25	5	0.25	{10,9,8,7,6} vs. {1,2,3,4,5}	-.139
0.251–0.30	6	0	{10,9,8,7} vs. {1,2,3,4,5,6}	.108
0.301–0.35	7	0	{10,9,8} vs. {1,2,3,4,5,6,7}	.343
0.351–0.85	8	0.5	{10,9} vs. {1,2,3,4,5,6,7,8}	.534
0.851–1.6	9	1	10 vs. {1,2,3,4,5,6,7,8,9}	.563
>1.61	10	1		



cussed and some real data examples tested. Clearly, such a change point test describes the exposure-response of the population only. Further investigations are required to demonstrate that this simple approach can be utilized to estimate the center of the individual-level change point distribution. Moreover, the above approach is not limited to change point alternatives: other trend alternatives, such as Williams-type trends [29], can be assumed as well.

### Competing interests

The authors declare that they have no competing interests.

### Authors' contributions

LAH adapted the multiple contrast tests on epidemiological case-control studies and performed part of the simulation study. MV selected, analyzed, and interpreted the epidemiological examples and designed the simulation study. TH developed the majority voting algorithm and wrote the R program.

### Appendix A

#### Formulation contrast tests for the relative risk

The estimators for the relative risk (RR) of each exposure group versus unexposed ( $j = 1$ ) are:

$RR_{j1} = \frac{n_{j1}/n_j}{n_{11}/n_1}$ ,  $j = 2, \dots, k$ . The single contrast tests can be formulated for relative risks, for example for the reverse

$$\text{Helmert's contrast: } t_{revHelmert} = \frac{-kp_1 + \sum_{j=2}^k p_j}{\sqrt{p(1-p) \left( \sum_{j=2}^k 1/n_j + k^2/n_1 \right)}}$$

$$t_{revHelmert}^{RR} = \frac{-k \frac{n_{11}}{n_1} + \sum_{j=2}^k \frac{n_{j1}}{n_j}}{\sqrt{p(1-p) \left( \sum_{j=2}^k 1/n_j + k^2/n_1 \right)}} = \frac{-k + \sum_{j=2}^k \frac{n_{j1} n_{11}}{n_j n_1}}{\frac{n_{11}}{n_{11}} \sqrt{p(1-p) \left( \sum_{j=2}^k 1/n_j + k^2/n_1 \right)}} = \frac{-k + \sum_{j=2}^k RR_{j1}}{\frac{n_{11}}{n_{11}} \sqrt{p(1-p) \left( \sum_{j=2}^k 1/n_j + k^2/n_1 \right)}}$$

For general contrasts hold true

$$t_{SingleContrast}^{RR} = \frac{c_1 + \sum_{j=2}^k c_j RR_{j1}}{\frac{n_{11}}{n_{11}} \sqrt{p(1-p) \left( \sum_{j=1}^k c_j^2 / n_j \right)}}$$

### Appendix B

The ORIC approach for three binomials and the change point alternative. The three models are:

$M_0 \{H_0: \pi_1 = \pi_2 = \pi_3\}$ ,  $M_1 \{H_{M_1}: \pi_1 = \pi_2 < \pi_3\}$ ,  $M_2 \{H_{M_2}: \pi_1 < \pi_2 = \pi_3\}$ . The likelihood is

$$L(\pi) = \frac{n_1!}{n_{11}!(n_1 - n_{11})!} \pi_1^{n_{11}} (1 - \pi_1)^{n_1 - n_{11}} \frac{n_2!}{n_{21}!(n_2 - n_{21})!} \pi_2^{n_{21}} (1 - \pi_2)^{n_2 - n_{21}} \frac{n_3!}{n_{31}!(n_3 - n_{31})!} \pi_3^{n_{31}} (1 - \pi_3)^{n_3 - n_{31}}$$

. With the expected values  $\pi_j$  and their crude estimators:

$$p_1 = n_{11}/n_1, \quad p_2 = n_{21}/n_2, \quad p_3 = n_{31}/n_3.$$

The  $\tilde{p}_j$  are the maximum likelihood estimates under the

simple order restriction:  $\tilde{p}_j = \min_{t:t \geq j} \max_{s:s \leq i} \frac{\sum_{j=s}^t w_j p_j}{\sum_{s=j}^t w_j}$ . The like-

lihood for the null-model  $M_0$  is:

$$L(\tilde{p}_{H_0}) = \prod_{j=1}^3 \frac{n_j!}{n_{j1}!(n_j - n_{j1})!} \tilde{p}_{H_0}^{n_{j1} + n_{21} + n_{31}} (1 - \tilde{p}_{H_0})^{n_1 + n_2 + n_3 - (n_{11} + n_{21} + n_{31})}$$

where  $\tilde{p}_{H_0} = \frac{n_{11} + n_{21} + n_{31}}{n_1 + n_2 + n_3} = \frac{w_1 p_1 + w_2 p_2 + w_3 p_3}{w_1 + w_2 + w_3}$  provided  $w_j = n_j$

The likelihood for the model  $M_1$  is:

$$L(\tilde{p}_{M_1}) = \prod_{j=1}^3 \frac{n_j!}{n_{j1}!(n_j - n_{j1})!} \tilde{p}_{(12)}^{n_{11} + n_{21}} (1 - \tilde{p}_{(12)})^{n_1 + n_2 - (n_{11} + n_{21})} \tilde{p}_3^{n_{31}} (1 - \tilde{p}_3)^{n_3 - n_{31}}$$

where  $\tilde{p}_{(12)} = \frac{n_{11} + n_{21}}{n_1 + n_2}$ , for

$$p_{(12)} < p_3 \Rightarrow \tilde{p}_{12} = p_{(12)}, \tilde{p}_3 = p_3$$

and

$$\tilde{p}_{(12)} \geq p_3 \Rightarrow \tilde{p}_{12} = \tilde{p}_3 = \frac{w_{(12)} p_{(12)} + w_3 p_3}{w_{(12)} + w_3} = \frac{n_{11} + n_{21} + n_{31}}{n_1 + n_2 + n_3}.$$

The likelihood for the model  $M_2$  is:

$$L(\tilde{p}_{M_2}) = \prod_{j=1}^3 \frac{n_j!}{n_{j1}!(n_j - n_{j1})!} \tilde{p}_{(23)}^{n_{21} + n_{31}} (1 - \tilde{p}_{(23)})^{n_2 + n_3 - (n_{21} + n_{31})} \tilde{p}_1^{n_{11}} (1 - \tilde{p}_1)^{n_1 - n_{11}}$$

where  $\tilde{p}_{(23)} = \frac{n_{21} + n_{31}}{n_2 + n_3}$  for

$$p_1 < \tilde{p}_{(23)} \Rightarrow \tilde{p}_1 = p_1, \tilde{p}_{(23)} = \tilde{p}_{(23)}$$

and

$$p_1 \geq \tilde{p}_{(23)} \Rightarrow \tilde{p}_1 = \tilde{p}_{(23)} = \frac{w_1 p_1 + w_{(23)} \tilde{p}_{(23)}}{w_1 + w_{(23)}} = \frac{n_{11} + n_{21} + n_{31}}{n_1 + n_2 + n_3}.$$

The model-specific ORIC are:  $ORIC(M_r) = \log L(\tilde{\pi}_{M_r}) - \text{penalty}(M_r)$ .

Where the penalty terms are  $\text{penalty}(M_r) = \sum i P\{i, j, w(M_r)\}$



With

$$w(M_0) = n_1 + n_2 + n_3.$$

$$w(M_1) = n_1 + n_2, n_3.$$

$$w(M_2) = n_1, n_2 + n_3.$$

$$\text{Because } P\{1, 1, w(M_0)\} = 1 \quad \text{ORIC}(M_0) = L(P\{1, 1, w(M_0)\} = 1 \text{ ORIC}(M_0) = L(\tilde{p}_{H_0}) - 1) - 1$$

Because

$$P\{1, 2, w(M_1)\} = \frac{1}{2} \quad P\{2, 2, w(M_1)\} = \frac{1}{2} \quad \text{ORIC}(M_1) = L(\tilde{p}_{M_1}) - \frac{3}{2}$$

Because

$$P\{1, 2, w(M_2)\} = \frac{1}{2} \quad P\{2, 2, w(M_2)\} = \frac{1}{2} \quad \text{ORIC}(M_2) = L(\tilde{p}_{M_2}) - \frac{3}{2}$$

## Additional material

### Additional file 1

**Additional simulation results.** Contains three tables with simulated correct classification results

Click here for file

[<http://www.biomedcentral.com/content/supplementary/1742-5573-6-1-S1.pdf>]

### Additional file 2

**R package bindosres.** The R package bindosres which can be installed in R via "install packages from local zip files"

Click here for file

[<http://www.biomedcentral.com/content/supplementary/1742-5573-6-1-S2.gz>]

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# Exhibit 154



# Dose-Response and Trend Analysis in Epidemiology: Alternatives to Categorical Analysis

Sander Greenland

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Standard categorical analysis is based on an unrealistic model for dose-response and trends and does not make efficient use of within-category information. This paper describes two classes of simple alternatives that can be implemented with any regression software: fractional polynomial regression and spline regression. These methods are illustrated in a problem of esti-

imating historical trends in human immunodeficiency virus incidence. Fractional polynomial and spline regression are especially valuable when important nonlinearities are anticipated and software for more general nonparametric regression approaches is not available. (Epidemiology 1995;6:356-365)

**Keywords:** biostatistics, epidemiologic methods, logistic regression, relative risk, risk assessment.

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Dose-response and trend analyses in epidemiology are commonly conducted in a very simple and often naive fashion. At worst, authors only conduct a trend test such as the Mantel test, or fit a regression model with a single exposure term and test the significance of the slope (coefficient) for the exposure. Such an approach can be very misleading because, in essence, it *assumes* that the dose-response or trend curve follows a specific model form (usually logistic).<sup>1</sup>

More desirably, authors may break the range of the study exposure into categories and look for trends in the category-specific coefficients or relative risks.<sup>2</sup> Such an approach can be adequate if numbers allow the use of categories that reflect biologically homogeneous response groups or are very narrow. Too often, however, categories are chosen via a mechanical algorithm such as the percentile method, in which equal-sized categories (tertiles, quartiles, or quintiles) are chosen in the belief that such an approach will maximize accuracy and minimize subjectivity in the analysis. The potential pitfalls of percentiles are most dramatic when most subjects are exposed in a very narrow range or when exposure effects are limited to extreme ends of the exposure scale, such as very low nutrient levels or very high occupational exposure levels. In such situations, individuals placed at elevated risk by exposure will be submerged among lower-risk members of their percentile category. This hazard can sometimes be mitigated by basing percentiles on the

case distribution, rather than the distribution of all subjects, but would be desirable to avoid altogether.

Many authors have recommended nonparametric regression as a means of avoiding the categorization problem altogether.<sup>1,3,4</sup> This is a preferable approach, especially when one can safely assume nothing about the form of the trend or the exposure-disease (dose-response) relation. It is mildly hindered by lack of widely available software, although this obstacle is gradually disappearing. Another occasional drawback is that the computing limits (maximum numbers of covariates and subjects) for nonparametric regression tend to be much lower than those for conventional regression. Because of these limits, and because several books on the topic are available,<sup>3-5</sup> I will not discuss nonparametric regression here. Instead, I will describe two alternative curve-fitting methods that seem under-used in epidemiologic research. The two methods, fractional polynomial regression and spline regression, can be performed with any regression program simply by adding some transformed exposure variables to the regression. Both methods are intermediate between simple regression and nonparametric regression in behavior, with fractional polynomials closer to simple regression (but still a vast improvement) and spline regression falling closer to nonparametric regression (so close that it may be considered an approximation to nonparametric regression). As will be discussed below, both categorical analysis and splines can be viewed as special types of category-specific regression, but splines are based on more realistic category-specific models.

In what follows, I will denote the exposure of interest by  $x$ . All points apply even when  $x$  is only a time variable for which trends are to be plotted, or a confounder for which close control is desired. The following analysis of secular trends in human immunodeficiency virus (HIV) infection incidence will serve to illustrate all of the

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TABLE 1. New AIDS Diagnoses in Los Angeles County through 1992 Reported by 1994 among White Non-Hispanic Men Who Have Sex with Men Reporting No Injection Drug Use, 1951–1960 Birth Cohort, and Naive HIV Incidence-Rate Estimates

Year	Years since 1976 (j)	New AIDS Cases (y)	White Non-Hispanic Person-Years, in Thousands (n <sub>x</sub> )	Naive HIV Rate Estimate*
1979	3	0	362	0
1980	4	0	360	100
1981	5	4	355	519
1982	6	10	353	76
1983	7	46	351	728
1984	8	92	349	1,744
1985	9	201	348	433
1986	10	329	348	65
1987	11	456	348	1,820
1988	12	476	347	111
1989	13	606	347	2,013
1990	14	642	348	192
1991	15	791	344	57
1992	16	645	339	119
Total		4,298		

\* Number of infections per 100,000 person-years (see Appendix).

methods discussed in this paper. Throughout, the focus will be on estimation of the shape of dose-response or trend; a companion article<sup>6</sup> describes the advantages of splines in testing for dose-response and trends.

General Description of Example

A major task in the study of acquired immunodeficiency syndrome (AIDS) is estimation of historical trends in HIV infection incidence.<sup>7</sup> Table 1 presents the 4,298 AIDS cases diagnosed in Los Angeles County through 1992 and reported by 1994 among white non-Hispanic men who have sex with men (MSM) born 1951–1960 who reported no injection drug use (IDU). Because there are no reliable data on cohort-specific prevalences of behaviors that define HIV transmission groups (such as sexual behavior), the HIV rates refer to the number of HIV MSM cases that reported no injection drug use among white non-Hispanic men born 1951–1960, rather than the number of HIV cases among non-IDU white non-Hispanic MSM born 1951–1960.

Because HIV incidence has not been directly observed, historical HIV incidence is computed from observed AIDS incidence using estimates of the distribution of incubation time from HIV infection to AIDS diagnosis.<sup>7,8</sup> The final column of Table 1 presents HIV rate estimates derived from a backcalculation equation, given in the Appendix, that relates AIDS to HIV incidence. These naive estimates involve no model or grouping of years. As a result, they present a noisy pattern and would fluctuate wildly in response to minor changes in the data or the estimation method.

More stable estimates require use of a model for the HIV rates. In the examples below, a series of models for these rates will be fitted via a Poisson regression method described in detail elsewhere<sup>8,9</sup> and summarized in the Appendix. The important elements for the present dis-

cussion are the structural forms of the models. To describe them, let  $x$  be years since 1976 (1976, then, is year 0, which is commonly taken as the start of the epidemic),  $n_x$  the person-years at risk in year  $x$ , and  $r_x$  the HIV incidence rate in year  $x$ . The simple log-linear model

$$r_x = \exp(\alpha + \beta x) \tag{1}$$

is out of the question, because it implies that HIV incidence rates continued to increase exponentially through the 1980s and beyond, contrary to extensive evidence of leveling and decline in the 1980s.<sup>5</sup> Hence  $\beta x$  must be replaced by a more flexible set of trend terms. Figure 1 presents the fitted HIV incidence rates derived from Table 1 using five different choices for these terms, each with four coefficients (beyond the intercept): (1) four category indicators for five categories (*dotted line*);

(2) fractional polynomial with four powers of untransformed time (*short dashes*); (3) fractional polynomial with four powers of log time (*solid curve*); (4) linear spline with four categories of log time (*long dashes*); (5) quadratic spline with three categories of log time (*solid curve* again—it almost perfectly agrees with the fractional polynomial with log time). The remainder of the paper will describe each choice in detail.

As a special caution in interpreting Figure 1, note that the very long incubation time between HIV infection and AIDS incidence (median time on the order of 10 or more years<sup>10</sup>) implies that the data in Table 1 contain almost no information on HIV incidence after 1989.

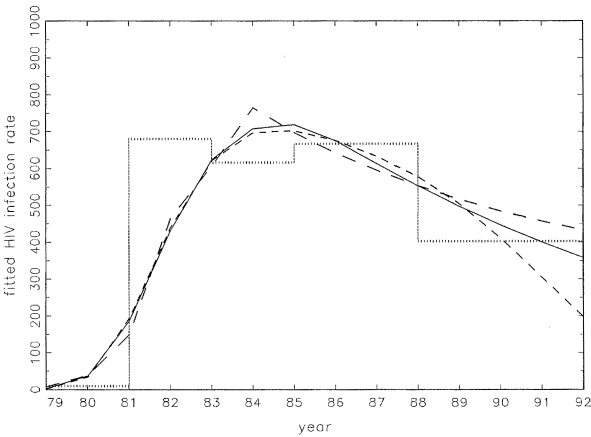


FIGURE 1. Fitted HIV infection incidence in Los Angeles County, 1979–1992: non-IDU MSM cases per 100,000 person-years among white non-Hispanic men born 1951–1960. *Short dashes*: fractional polynomial curve in untransformed time; *solid curve*: fractional polynomial curve in log time and (coinciding) quadratic spline curve; *dotted line*: step function from category indicators; *long dashes*: linear spline.



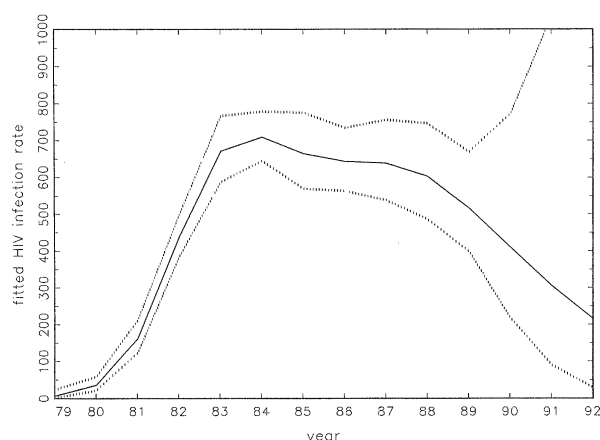


FIGURE 2. Fitted penalized spline HIV incidence curve (solid curve) with pointwise 95% confidence limits (dotted curves).

Thus, after 1989 the curves are little more than extrapolations from previous years (hence the increasing divergence beyond 1989). On the other hand, the data do provide a reasonable amount of information on HIV incidence before 1989. This point is illustrated in Figure 2, which shows the fitted curve and pointwise confidence limits obtained by using a penalized spline smoother as part of a multivariate model for HIV incidence<sup>9</sup> (the kinks in these three curves are artifacts of the graphing program). As a secondary caution, note that the curves in Figure 1 cannot be obtained by fitting models to the naive HIV rates in Table 1; all fitting must instead be done via backcalculation from observed AIDS incidence (Appendix Eq A1).

### Fractional Polynomial Regression

Many authors recommend that one try to examine polynomial terms (at least a quadratic term  $x^2$ ) in addition to the basic linear term  $x$  in the dose-response model.<sup>1</sup> There are problems with polynomial regression, however. Although in theory with enough polynomial terms one can approximate any smooth curve, in reality the number of terms required may be so large as to result in numerically unstable estimates. Polynomials greater than quadratic tend to produce artifactual turns in the fitted curve, whereas quadratics have extremely limited flexibility.

Recently, Royston and Altman<sup>11</sup> have emphasized that a great deal more flexibility and stability can be obtained by examining fractional and inverse powers of  $x$ , such as  $x^{-2}$ ,  $x^{-1}$ ,  $x^{-1/2}$ , and  $x^{1/2}$  in addition to  $x$  and  $x^2$ . (Terms of the form  $x^j[\ln(x)]^l$  are also included in the family of curves considered by Royston and Altman, but these cannot be used if  $x$  can be zero or negative.) Royston and Altman point out that models containing as few as three different powers of  $x$  between  $x^{-2}$  and  $x^2$  encompass a dramatic range of shapes.

Fractional polynomials do have important limitations.<sup>12,13</sup> For example,  $x$  cannot be negative if fractional

powers are used, and the results will be sensitive to the position of the zero-level of exposure  $x$ . Thus, fractional polynomials may be problematic if  $x$  is not ratio scaled; that is, it is advisable that  $x$  have an absolute zero level (unexposed level) and be coded so that this level is zero.<sup>12</sup> Nonetheless, many, if not most, epidemiologic exposures have an absolute zero, so that this limitation may be of infrequent practical importance. (If  $x$  can be negative, Royston and Altman recommend adding a positive number to force it to be positive, but this approach essentially introduces a new nonlinear parameter into the model, because the optimal number to add is unknown.)

In the HIV example,  $x$  does have an absolute zero: it is the time at which the epidemic started, which has not been precisely determined but is customarily taken to be 1976. A similar problem (of an absolute but imprecisely known zero) arises when using age in studies of adult noninfectious diseases: Age is often a surrogate for time since start of an unmeasured background exposure (for example, hormones) or etiologic process. In such situations, it may be advisable to replace age by a more biologically relevant time scale in which risk becomes nonzero only after time zero. For example, time since puberty could serve as such a scale in certain studies of cancers of the reproductive system.

Another problem, one which also afflicts polynomial regression, is how to decide which terms to include. Royston and Altman propose a special stepwise procedure, which (like all stepwise procedures) is questionable in concept and requires special programming. Ideally, one should specify in advance the shape of curves one would want the fitted model to encompass. To do so, however, requires a sense of what shapes are encompassed by each power of  $x$ . For most epidemiologic purposes, it suffices to recall that, as  $x$  increases above 0,  $x^2$  starts more slowly but soon increases more rapidly than  $x$ , and that  $x^{1/2}$  starts more rapidly but soon increases more slowly than  $x$ . From this, a simple qualitative dose-response analysis might always include  $x$  (the linear term) and then:

1. Include  $x^2$  if one expects the slope of the trend or dose-response curve (that is, the steepness, or effect per unit exposure) to increase in absolute value as exposure increases (as with cigarettes per day and lung cancer<sup>14</sup>), or if one expects the curve to change direction.
2. Include  $x^{1/2}$  if one expects the slope to decrease in absolute value as exposure increases.
3. Include both  $x^{1/2}$  and  $x^2$  if one wants to allow for either possibility.

One may, of course, use a higher power of  $x$  in place of  $x^2$  and a lower power of  $x$  in place of  $x^{1/2}$  if one expects more rapid changes in slope over the range of exposure, and one may include more terms if greater flexibility is desired.

If  $x$  can only be positive (as with typical cardiovascular and anthropometric measurements),  $\ln(x)$  can be



used in place of  $x^{1/2}$  to yield a curve with a very gradually declining slope. In fact, if one uses a logistic or exponential (log-linear) model for risks or rates and  $x$  can only be positive, it can be argued that  $\ln(x)$  should be included in all dose-response and trend analyses. This is because the use of  $x$  alone in such models implies that the rate, risk, or odds ratio for exposure level  $x$  vs zero is  $e^{\beta x}$ , which increases exponentially with  $x$  if  $\beta > 0$ . Use of  $\ln(x)$  instead yields a rate, risk, or odds ratio of  $\exp[\beta \ln(x)] = x^\beta$ , which can increase much less rapidly than exponentially and can even increase less than linearly if  $0 < \beta < 1$ .

#### Example

The *short dashes* in Figure 1 trace the fitted curve obtained from Table 1 using:

$$r_x = \exp(\alpha + \beta_1 x^{1/2} + \beta_2 x + \beta_3 x^{3/2} + \beta_4 x^2).$$

A virtually identical curve was obtained using  $x^3$  instead of  $x^{3/2}$ . The *solid line* traces the fitted curve obtained using powers of  $\ln(x)$  in place of powers of  $x$  as the time covariate. Both curves exhibit essentially exponential growth until 1982, followed by rapid slowing with a peak in 1984, and gradual decline thereafter.

Although fractional polynomials with only two or three exposure terms can produce quite a variety of curves, one should be aware when examining such curves that their exact shape and location can be strongly influenced by one or a few data points. In particular, the fitted values for a point can be strongly influenced by data at points far away on the graph.<sup>13</sup> This is also a problem with curves fit by quadratic or cubic regression, and with the single slope produced by a simple regression with only  $x$  (the linear term) included. Thus, it is especially important to evaluate regressions with few exposure terms using influence analysis, which involves seeing how much results change when the most influential data points are deleted from the analysis (in the present HIV example, the basic conclusions are unchanged by single deletions). Inclusion of confidence limits in the curve graph can also help indicate what portions of the curve are poorly estimated. (Methods for constructing confidence limits are described in the Discussion.)

### Spline Regression

#### CATEGORY INDICATORS REVISITED

Consider ordinary categorical dose-response analysis<sup>2</sup> from the following perspective: One divides the observed range of exposure  $x$  into  $K$  categories indexed by  $k = 1, \dots, K$  with  $K - 1$  internal boundaries  $c_1, \dots, c_{K-1}$ . Then, within each category, one fits a completely horizontal line as the dose-response "curve" relating exposure to the outcome within the category. For example, in categorical logistic regression, one simultaneously fits  $K$  category-specific models for the logit (log odds) of risk  $R$ :

$$\text{logit}(R|x \text{ in category } k) = \alpha_k^*, k = 1, \dots, K, \quad (2)$$

which says that  $x$  has *no effect whatsoever within categories*, no matter how large its effect between categories!

To illustrate, suppose  $x$  is daily intake of ascorbic acid,  $R$  is mortality risk, and the internal boundaries for  $x$  are at 20, 50, and 100 mg per day, with the boundaries included in the lower category. The categorical dose-response model then says that there is no difference in risk between 0 and 20 mg per day but allows there to be an arbitrarily large jump in risk between 20 and 21 mg per day. This is biologically absurd, given that 0 mg per day represents a relatively rapidly fatal deficiency state, 20 mg per day does not, and the difference between 20 and 21 mg per day is biologically trivial. Although a categorical model can be viewed as providing estimates of average risk within categories, one should question the value of averaging risks that are known to be as disparate as those for 0 and 20 mg per day of ascorbic acid. Furthermore, under nonlinear models, the estimates of average risk provided by category-indicator regression can produce a biased impression of the exposure-specific dose-response curve.<sup>15</sup>

The preceding type of model, called a step function, is precisely what one is fitting when one breaks exposure into categories and then fits a model with  $K - 1$  indicator variables  $i_2, \dots, i_K$ , where  $i_k = 1$  if  $x$  is in category  $k$ , 0 otherwise:

$$\text{logit}(R|x) = \alpha_1 + \alpha_2 i_2 + \dots + \alpha_K i_K. \quad (3)$$

Here,  $\alpha_1 = \alpha_1^*$  and  $\alpha_k = \alpha_k^* - \alpha_1^*$  for  $k > 1$ . The results from such a model will not be misleading if risk changes little within categories. Unfortunately, selection of category boundaries based on percentiles in no way guarantees that this criterion will be met. In fact, use of percentiles virtually guarantees that the criterion will be violated if most subjects are concentrated within a narrow subrange of exposure and the exposure does have a large effect beyond that subrange.

The only way to ensure constancy of risk within categories is to use very narrow categories. This will often yield many more categories than the standard four or five—perhaps as many as 10, or even 20. If so, numbers may become so small within categories that the category-specific estimates are uselessly unstable, as in Table 1. Conventional recommendations (of four or five categories) seek to minimize variance by using few categories, but they unrealistically assume that boundaries will be set in an ideal fashion. If, however, the boundaries are not well chosen, bias will result. The variance-bias tension is especially severe in categorical dose-response modeling because of the unrealistic model that underlies the analysis.

#### Example

The *small dots* in Figure 1 trace the step function obtained by fitting the categorical model:

$$r_x = \exp(\alpha_1 + \alpha_2 i_2 + \alpha_3 i_3 + \alpha_4 i_4 + \alpha_5 i_5),$$

where  $i_2, i_3, i_4, i_5$  are indicators for the categories 1981–1982, 1983–1984, 1985–1987, and  $\geq 1988$ . The later



categories are broader because of the declining stability of the estimates over time. The visual impression provided by these estimates is less accurate than that from the other curves, failing to locate well the early climb and later decline in rates. The curve produced by connecting the midpoints instead of the ends of the categories (not shown) is a little better but is still not as plausible as the smooth curves. Narrower categories (not shown) were tried but failed to help, and instead produced erratically fluctuating steps. (Note that if one used categories based on the AIDS case percentiles from Table 1, the results would be disastrous: the first quartile extends through 1987, so that the fitted step function would represent the dramatic 1980–1987 trend by one constant rate!)

#### LINEAR SPLINE REGRESSION

How can one avoid the absurdity, pitfalls, and tensions of category-indicator analysis for continuous variables? One simple solution is to allow the within-category lines to have nonzero slopes, so that the model will allow risk to vary *within* as well as *between* categories. Furthermore, we can fit these lines in such a way that there is no sudden jump in risk across category boundaries, so that fitted risk changes in a continuous manner within and across categories. The simplest method for doing so is called linear spline regression, which can be performed with conventional regression programs.

For logistic regression, the objective might be to simultaneously fit the  $K$  category-specific linear models:

$$\text{logit}(R|x \text{ in category } k) = \alpha_k^* + \beta_k^* x. \quad (4)$$

We should want these  $K$  models to fit together in a biologically sensible way, meaning that we want continuity (no sudden jumps) in risk across the category boundaries. This in turn requires any adjacent pair of category-specific models to predict the same risk at their common boundary  $j$ . For a logistic model, this means we must have:

$$\text{logit}(R|x = c_k) = \alpha_k^* + \beta_k^* c_k = \alpha_{k+1}^* + \beta_{k+1}^* c_k \quad (5)$$

for all  $k$  less than  $K$ . One way to force Eqs 4 and 5 to hold for all  $k$  less than  $K$  is to fit the following *linear spline model* to all of the data:

$$\text{logit}(R|x) = \alpha + \beta_1 x + \beta_2 s_2 + \cdots + \beta_K s_K, \quad (6)$$

where  $s_k = 0$  if  $x \leq c_k$ ,  $x - c_k$  if  $x > c_k$ .  $s_k$  is sometimes called the positive part of  $x - c_k$  and can also be defined as  $s_k = \max(0, x - c_k)$ . The parameters in Eq 6 are simple functions of the parameters in the  $K$  models in Eq 4:  $\alpha = \alpha_1^*$  and  $\beta_1 = \beta_1^*$ , whereas for  $k > 1$ ,  $\beta_k = \beta_k^* - \beta_{k-1}^*$  is the change in the slope of dose-response in going from category  $k - 1$  to category  $k$ . The graph of Eq 6 will look like a series of connected line segments.

#### Example

The *long dashes* in Figure 1 trace the linear spline obtained by fitting the model:

$$r_x = \exp(\alpha + \beta_1 \ln(x) + \beta_2 s_2 + \beta_3 s_3 + \beta_4 s_4)$$

where

$$s_2 = 0 \text{ if } x \leq 6, \ln(x) - \ln(6) \text{ if } x > 6,$$

$$s_3 = 0 \text{ if } x \leq 8, \ln(x) - \ln(8) \text{ if } x > 8,$$

and

$$s_4 = 0 \text{ if } x \leq 11, \ln(x) - \ln(11) \text{ if } x > 11$$

( $x = 6, 8, 11$  correspond to 1982, 1984, 1987). Apart from the artificially sharp peak in 1984, this model conveys essentially the same pattern as the fractional polynomial curves.

The general idea exemplified by Eqs 4–6 is to fit regression models simultaneously within each category, subject to constraints that maintain reasonable relations across the strata. These constraints also keep the analysis parsimonious. With  $K$  separate category-specific linear regressions, the total number of coefficients fit would have been  $2K$  ( $K$  intercepts and  $K$  slopes). Nevertheless, the intercepts  $\alpha_2, \dots, \alpha_K$  are eliminated because of the continuity (no-jump) constraint, leaving only one intercept. The total number of parameters in Eq 6 is thus  $K + 1$ , only one more than the step function model for the same categories (Eq 3). Furthermore, unlike the step function (Eq 3), the linear spline (Eq 6) does not depend on risk being constant within categories for validity and thus can be used with fewer categories than required for valid use of the step function (Eq 3).

#### MORE GENERAL SPLINE REGRESSION

Although a linear spline function is a dramatic improvement over a step function, it still does not have full biological plausibility because of the sharp bends (kinks) at the boundaries where the slope of the function abruptly changes. Also, linear-spline regression can suffer from instabilities and sensitivities to choice of category boundaries, although usually not as severely as category-indicator regression. To address these problems, we can create a curve with no sharp bends and a more smooth, plausible appearance simply by adding a quadratic term to each category-specific model, for example:

$$\text{logit}(R|x \text{ in category } k) = \alpha_k^* + \beta_k^* x + \gamma_k^* x^2. \quad (7)$$

As before, we want no jumps, which means adjacent category-specific models must agree at their common boundary:

$$\begin{aligned} \text{logit}(R|x = c_k) &= \alpha_k^* + \beta_k^* c_k + \gamma_k^* c_k^2 \\ &= \alpha_{k+1}^* + \beta_{k+1}^* c_k + \gamma_{k+1}^* c_k^2. \end{aligned} \quad (8)$$

To obtain a smooth appearance, we also want adjacent models to have the same slope (derivative) at their common boundary, which corresponds to requiring that:

$$\beta_k^* + 2\gamma_k^* c_k = \beta_{k+1}^* + 2\gamma_{k+1}^* c_k. \quad (9)$$



Simultaneously fitting the  $K$  category-specific quadratic models (Eq 7) subject to the continuity constraint (Eq 8) and the smoothness (slope) constraint (Eq 9) is equivalent to fitting the single *quadratic spline model*:

$$\text{logit}(R|x) = \alpha + \beta x + \gamma_1 x^2 + \gamma_2 s_2^2 + \cdots + \gamma_K s_K^2, \quad (10)$$

where  $\alpha = \alpha_1^*$ ,  $\beta = \beta_1^*$ ,  $\gamma_1 = \gamma_1^*$ , and, for  $k > 1$ ,  $\gamma_k = \gamma_k^* - \gamma_{k-1}^*$  is the change in the quadratic term (departure from linearity) of the dose-response function in going from category  $k-1$  to category  $k$ . This quadratic spline model (Eq 10) has only one more parameter than the linear spline model for the same categories (Eq 6). Furthermore, it would ordinarily require fewer categories for accuracy than the linear spline model, so that in practice no more parameters are needed than for the latter model. As with the linear spline, it can easily be fit with conventional regression programs.

#### Example

In addition to tracing the log-time fractional polynomial curve, the *solid curve* in Figure 1 coincides with the quadratic spline obtained by fitting the model:

$$r_x = \exp(\alpha + \beta_1 \ln(x) + \gamma_1 \ln(x)^2 + \gamma_2 s_2^2 + \gamma_3 s_3^2),$$

where

$$s_2 = 0 \text{ if } x \leq 7, \ln(x) - \ln(7) \quad \text{if } x > 7,$$

and

$$s_3 = 0 \text{ if } x \leq 10, \ln(x) - \ln(10) \quad \text{if } x > 10$$

( $x = 7, 10$  correspond to 1983, 1986).

Like higher-order polynomials, quadratic splines can suffer from odd behavior in open-ended tails of the exposure distribution. When this happens, we can further reduce the number of parameters and improve tail behavior by restricting the fitted curve to be linear in open-ended categories. To restrict the lower tail, one need only drop  $x^2$  from the model. To restrict the upper tail, one drops  $s_K^2$  from Model 10 and replaces the remaining  $s_k^2$  by  $s_k^2 - s_K^2$ ; one also replaces  $x^2$  by  $x^2 - s_K^2$  if the lower tail is not restricted. The quadratic spline with both tails restricted to be linear is:

$$\begin{aligned} \text{logit}(R|x) = & \alpha + \beta x + \gamma_2 (s_2^2 - s_K^2) \\ & + \cdots + \gamma_{K-1} (s_{K-1}^2 - s_K^2). \end{aligned} \quad (11)$$

This model has only  $K$  coefficients including the intercept. In other words, it has exactly the same number of parameters as the crude step-function model (Eq 3), given that the same number of categories are used. Yet, unlike the step function, it can reproduce a wide variety of smooth curves.

#### Example

Because of its closeness to the other curves, Figure 1 omits the curve obtained by fitting the restricted quadratic spline:

$$\begin{aligned} r_x = \exp[ & \alpha + \beta_1 \ln(x) + \gamma_2 (s_2^2 - s_5^2) \\ & + \gamma_3 (s_3^2 - s_5^2) + \gamma_4 (s_4^2 - s_5^2)] \end{aligned}$$

where

$$s_2 = 0 \text{ if } x \leq 5, \ln(x) - \ln(5) \quad \text{if } x > 5,$$

$$s_3 = 0 \text{ if } x \leq 7, \ln(x) - \ln(7) \quad \text{if } x > 7,$$

$$s_4 = 0 \text{ if } x \leq 9, \ln(x) - \ln(9) \quad \text{if } x > 9,$$

$$s_5 = 0 \text{ if } x \leq 12, \ln(x) - \ln(12) \quad \text{if } x > 12$$

(these spline terms are based on the same categories as the earlier category-indicator model). This curve is very similar to the linear-spline curve, but rounded at the peak and at other category boundaries.

The type of restricted spline just described should not be confused with so-called natural splines,<sup>5</sup> in which the fitted curve is restricted to be linear below the smallest and above the largest observed value of  $x$ . These natural splines have the same number of parameters as unrestricted splines. They are obtained by treating  $\min(x)$  and  $\max(x)$  as additional category boundaries and then fitting a restricted spline to the expanded set of  $K+2$  categories. Within the range of the data, the resulting curve is identical to that produced by the unrestricted spline.

As the reader may have surmised, one may further extend the category-specific models and constraints. The form preferred by most statisticians is the *cubic spline model*,<sup>16</sup> which in its unrestricted form may be written:

$$\begin{aligned} \text{logit}(R|x) = & \alpha + \beta x + \gamma x^2 + \delta_1 x^3 \\ & + \delta_2 s_2^3 + \cdots + \delta_K s_K^3, \end{aligned} \quad (12)$$

This model may be derived by adding a cubic term  $\delta_K^* x^3$  to the category-specific quadratic models (Eq 7) and then constraining the curves to be continuous and have equal slopes and second derivatives at the boundaries. The linear, quadratic, and cubic splines (Models 6 and 10–12) are all examples of *spline functions*, which are extensively used in the physical sciences and engineering but surprisingly rare in epidemiology. In the spline literature, the category boundaries  $c_1, \dots, c_{K-1}$  are called *knots* or *join points*, because they are the points at which the category-specific curves are tied together.<sup>3–5,16</sup> Natural cubic splines can be extended to produce a non-parametric smoother (called a cubic spline smoother) by placing a knot at each distinct exposure value and constraining the resulting saturated model with a penalty function.<sup>3–5</sup> It is also possible to constrain splines to produce only monotonic curves (that is, curves with no trend reversals).<sup>17</sup>

## Discussion

Some external evidence regarding the true epidemic curve in the example is available, all of it indicating that the smooth curves are better estimates than the category-indicator step function. Backcalculations based



on much more extensive national data<sup>8</sup> indicate that a single sharp peak occurred around 1984–1985. More generally, both theoretical<sup>5</sup> and simulation<sup>6</sup> evidence indicates that smooth splines have better statistical properties than comparably parameterized step functions. Of course, one may conduct both a traditional step-function analysis and a spline analysis. The primary point of this paper is simply that some sort of smooth curve fitting is advisable when the study covariate is continuous and numbers do not permit the use of narrow categories.

All of the above methods can be applied to multiple covariates in a model. When applied to confounders, however, fractional-polynomial and spline regressions can produce more complete confounder control than step functions; this is because only the former control for confounder effects *within* strata as well as across strata. Generalized additive models<sup>3,5</sup> offer the same advantage, but within a given computing capacity, fractional polynomials and splines can be fit to larger datasets with more subjects and covariates, and can be fit with any regression software.

#### UNEXPOSED SUBJECTS

An issue that often arises when  $x$  is a ratio-scaled exposure (such as alcohol consumption) is whether to delete the unexposed during dose-response analysis. As explained elsewhere,<sup>18</sup> deletion of the unexposed (zero-exposed) is not always the best approach and is, in fact, an inadvisable waste of information if the unexposed and exposed are comparable with respect to factors that affect validity (such as uncontrolled confounders and selection factors). An advantage of highly flexible models (with more than a few exposure terms) over simpler models is that the overall curve will usually be less influenced by the unexposed than in simpler models, and hence the decision to retain or delete the unexposed will be less momentous. In nonparametric regression with ample data, smoothing neighborhoods can be made small, in which case the unexposed will exert little or no influence on the curve beyond their immediate low-exposure neighborhood. For situations in which the validity of retaining the unexposed is in question, a separate indicator variable for the unexposed category can be entered in the regression, which will eliminate direct influence of the unexposed on the curve. If this is done, the resulting fitted curve will not necessarily pass through the fitted rate at  $x = 0$ , reflecting the fact that the unexposed have been effectively eliminated from the curve-fitting process. See Greenland and Poole<sup>18</sup> for further discussion of this approach.

#### CHOICE OF SPLINES

The improved smoothness of quadratic splines over linear splines leads me to prefer the former. In contrast, for epidemiologic purposes, there seem to be practical disadvantages and little if any advantage to using cubic splines instead of the quadratic splines. The primary disadvantage of cubic splines is that the cubic form of

the category-specific models can produce very strange shapes in broad categories and in open-ended categories. With any spline, category boundaries can be adjusted to remove anomalies, whereas end-category anomalies can be prevented or removed by further constraining the end-category models to be linear.<sup>16</sup> Unfortunately, for cubic splines, the latter constraint requires that more complicated covariates than the  $s_k$  defined above be used in the regression. A more minor disadvantage of cubic splines is the poor interpretability of the coefficients, especially when end constraints are needed.

With enough well-chosen categories, cubic splines can closely approximate virtually any smooth curve.<sup>4</sup> This advantage seems of doubtful utility for epidemiologic analysis, however, because plausible trends and dose-response curves are usually very simple in form compared with many of the response functions found in engineering and the physical sciences. The primary gain from using cubic splines is that they yield very smooth curves. Nonetheless, I have not yet found epidemiologic data for which a gain from using cubic instead of quadratic splines is graphically noticeable. In the HIV example used here, a 5-parameter cubic spline model with one knot in the mid-1980s yields nearly the same curve as the fractional polynomial and quadratic spline curves in Figure 1.

There are certain advantages to using unrestricted splines (such as Models 10 and 12) over splines with end-category restrictions (such as Model 11). An unrestricted quadratic spline contains the ordinary quadratic regression model (the model with  $x$  and  $x^2$  only) as a special case. Hence, the ordinary quadratic model can be checked against the more general unrestricted spline model (Eq 10) by testing the hypothesis that the spline coefficients are zero ( $\gamma_2 = \dots = \gamma_K = 0$  in Model 10). The restricted spline model (Eq 11) does not contain the quadratic model as a special case and so cannot be used in this way. Another drawback of restricted splines is that, perhaps counter to intuition, an end-category restriction can strongly affect the entire shape of the curve and enhance sensitivity of the overall shape to outliers. Nonetheless, restricted splines can be useful when linear end-category behavior is considered preferable to the nonmonotone end-category behavior that unrestricted splines can exhibit.

#### CHOICE OF CATEGORIES AND TERMS

There are various schools of thought regarding choice of categories for splines. One school seeks automatic methods that optimize some statistical criterion, such as minimizing a goodness-of-fit statistic or the cross-validation sum of squared residuals.<sup>3-5</sup> Others prefer simple visual assessment of smoothness: Start with many categories, then reduce their number and adjust boundaries so that implausible blips, dips, and irregularities are eliminated. Another visual approach (suggested by a referee) is to use the curve from a smoother to suggest where cutpoints should be. All of these approaches have limitations. Automated methods (such as stepwise selection of



knots) can invalidate conventional tests and confidence intervals for trends,<sup>16,19,20</sup> whereas visual choice runs the risk of introducing subjective biases. Visual choice does allow one to use vague prior information about curve shape. Absent such information, some authors prefer to use percentile categories<sup>16</sup>; the latter can perform adequately with splines even when they perform poorly with category indicators.<sup>6</sup>

The problems just discussed are even more acute for ordinary category-indicator regression, because the latter is so sensitive to category choice. In particular, use of percentile categories can severely harm power and precision in category-indicator regression if the exposure effect is concentrated in a tail of the exposure distribution.<sup>6</sup> Unlike category indicators, splines make use of within-category risk variation and so can be less sensitive to category choice,<sup>6</sup> although, like category indicators, they can be sensitive to choice of tail categories when those categories are open ended.

Fractional polynomial regression avoids the problem of category choice but instead faces an analogous problem in choice of terms. As with category choice, mechanical algorithms for choice of terms invalidate conventional tests and can perform badly in small to modest samples, whereas visual choice runs the risk of introducing subjective biases of the analyst. These choice issues also arise in nonparametric regression, in which the analyst must visually select a value for the smoothing parameter, or else have it chosen by an algorithm.<sup>3,5</sup> In sum, every dose-response or trend analysis (from conventional categorical to advanced nonparametric) must choose the degree of smoothness or complexity in the fitted curve via choice of categories, model terms, or smoothing parameter. Regardless of the approach one uses, graphical inspection of the final fitted curve will greatly aid in determining whether the choices made yielded credible or surprising results.

#### CUTOPOINT ANALYSIS AND THRESHOLDS

An issue of prominence in recent literature is that of choosing the proper cutpoint for dichotomous analysis of continuous exposures. Special concerns have been raised about "cutpoint bias," in which cutpoints are chosen to maximize significance or size of estimates.<sup>21,22</sup> Nonparametric curves and quadratic or cubic splines can largely finesse such issues by providing a single curve that simultaneously conveys rates or relative risks across the full range of exposure, without collapsing together disparate exposure levels. If there is a threshold for the exposure effect, it will be reflected by a steep portion of the smooth curve following a near-level portion. One should not, however, expect to see a single sharp (vertical) threshold point, because both exposure measurement error and individual variation in threshold will stretch out the threshold portion of the curve over some range of exposure.

#### DIAGNOSTICS

As with all regression, the methods discussed here (including conventional category-indicator regression, as

well as the alternatives) need to be coupled with regression diagnostics (model checking) such as tests of fit, residual analysis, and influence analysis. In nonparametric regression, the effects of influential data points tend to be visually more dramatic but more localized than in conventional parametric regression<sup>3</sup>; similar comments apply to the flexible alternatives discussed here. Marked influences often show up in tails of the fitted curve, which can be strongly pulled toward outlying points. Diagnostics such as influence analysis help distinguish observed patterns that are resistant to modest changes in the data from those that are "driven" by just one or two unusual data points. Sensitivity of patterns to conventional model assumptions can also be explored by comparing conventional results to the results from flexible models.

#### SAMPLE-SIZE CONSIDERATIONS

Fractional-polynomial and spline regression are *not* inherently large-sample techniques and can be applied with exact regression programs such as LogXact.<sup>23</sup> When applied in conjunction with large-sample (asymptotic) methods such as maximum-likelihood logistic regression, however, checks on sample size adequacy are advisable. Perhaps the easiest way of checking adequacy for maximum-likelihood logistic spline regression is to examine tabular cross-classifications based on the categories used to define the spline. By one rough criterion, if there are no product terms between exposure and other covariates, one should have at least five cases and five non-cases in each category when applying maximum-likelihood methods. I am not aware of an equally simple sample-size criterion for maximum-likelihood estimation of fractional polynomials.

#### CONFIDENCE LIMITS

For clarity, confidence limits were omitted from Figure 1, but in practice, it can be helpful to include them, as in Figure 2. Confidence limits for points on the regression curve are an option in many software packages, and these options can be invoked when fitting fractional polynomials and splines.

When such options are not available, one may compute limits directly using large-sample analogues of standard formulas.<sup>24</sup> As an illustration, suppose we want 95% limits at the point  $x$  under the quadratic logistic spline model (Eq 10). Define the full parameter vector  $\underline{\theta}$  as:

$$\underline{\theta} = (\theta_1, \dots, \theta_{K+2})' = (\alpha, \beta, \gamma_1, \gamma_2, \dots, \gamma_K)'$$

and the full covariate vector  $\underline{z}$  as:

$$\underline{z} = (z_1, \dots, z_{K+2})' = (1, x, x^2, s_2^2, \dots, s_K^2)'$$

Also, let  $\hat{c}_{ij}$  be the estimated covariance of the parameter estimates  $\hat{\theta}_i$  and  $\hat{\theta}_j$  (the  $\hat{c}_{ij}$  are available by requesting the covariance matrix output option from the regression



software). The fitted logit of risk  $\hat{l}_x$  at  $x$  is then the dot product of  $\underline{\hat{\theta}}$  and  $\underline{z}$ ,

$$\underline{\hat{\theta}}' \underline{z} = \sum_i \hat{\theta}_i z_i. \quad (13)$$

Approximate pointwise 95% limits for the risk at  $x$  are then given by:

$$\text{expit}(\underline{\hat{\theta}}' \underline{z} \pm 1.96 \hat{\phi}_x^{1/2}) \quad (14)$$

where  $\text{expit}(u) = e^u / (1 + e^u)$  is the logistic transform,  $\hat{\phi}_x$  is the estimated logit variance:

$$\hat{\phi}_x = \sum_i \sum_j \hat{c}_{ij} z_i z_j = \underline{z}' \hat{C} \underline{z}, \quad (15)$$

and  $\hat{C}$  is the estimated covariance matrix for  $\hat{\theta}$ .

To estimate the ratio of odds at two different exposure levels with full covariate vectors  $\underline{z}_1$  and  $\underline{z}_0$ , let  $\underline{d} = \underline{z}_1 - \underline{z}_0$  be the vector of differences of the  $\underline{z}_1$  and  $\underline{z}_0$  components. The fitted log odds ratio is then

$$\underline{\hat{\theta}}' \underline{d} = \sum_i \hat{\theta}_i d_i \quad (16)$$

and approximate 95% limits for the odds ratio are given by:

$$\text{exp}(\underline{\hat{\theta}}' \underline{d} \pm 1.96 \hat{\phi}_d^{1/2}) \quad (17)$$

where

$$\hat{\phi}_d = \sum_i \sum_j \hat{c}_{ij} d_i d_j = \underline{d}' \hat{C} \underline{d}. \quad (18)$$

For cohort data, approximate limits for the risk ratio can be obtained using the conditional method of Flanders and Rhodes,<sup>25</sup> whereas rate ratio limits can be obtained from an exponential-multiplicative rate model via Formulas 16–18.

The above formulas can be used when multiple covariates (exposure, confounders, and products among them) are present in the full covariate vector  $\underline{z}$ . The chief caution in their use is that they are large-sample approximations and can become inaccurate if the data are too limited. Computations are most easily performed using a matrix language such as GAUSS, MATLAB, SAS Proc Matrix, or S-Plus.

Approximate simultaneous 95% confidence limits can be constructed by replacing the normal 97.5th percentile of 1.96 by the square-root of the 97.5th percentile of a  $\chi^2$  distribution with degrees of freedom equal to the number of parameters ( $K + 2$  for the unrestricted quadratic spline). One should note, however, that these simultaneous limits do not provide an accurate 95% confidence band for the true regression curve; see section 3.82 of Hastie and Tibshirani<sup>3</sup> for a discussion of this point and

of bootstrap options for construction of confidence bands for the entire curve.

## Conclusion

The present paper has argued that epidemiologic analyses of dose-response and trend, as well as methods for control of continuous confounders, should be expanded beyond simple categorical and linear (single-coefficient) approaches to include flexible curves that make use of intracategory information. Such expansion can be accomplished with little difficulty via fractional polynomial regression and spline regression. These methods can be especially valuable when important nonlinearities are anticipated, as in studies of health effects of alcohol, nutrients, and other life-style factors.

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## Appendix

Assuming that migration and AIDS case reporting are nondifferential, the expectation  $\mu_j$  for the observed AIDS case count  $y_j$  in epidemic year  $j$  is:

$$\mu_j = q_j \sum_{x=1}^j p_{jx} n_x r_x \quad (\text{A1})$$

where  $q_j$  is the probability that someone diagnosed with AIDS in year  $j$  is reported by the study time (1994),  $p_{jx}$  is the probability that someone contracting HIV in year  $x$  is diagnosed with AIDS in year  $j$ ,  $n_x$  is the person-years at risk in year  $x$ , and  $r_x$  is the rate of non-IDU MSM HIV infections for the population in year  $x$ . In the examples,  $p_{jx}$  is taken from the stationary 3-parameter Weibull curve fit by Bacchetti *et al*<sup>8</sup> to the San Francisco hepatitis B cohort, with leveling of the hazard at its maximum. The denominators  $n_x$  are estimated from census data, whereas the  $q_j$  are estimated directly from the Los

Angeles County AIDS surveillance data, which supplies both diagnosis and reporting dates.

Given the  $p_{jx}$ ,  $n_x$ ,  $q_j$ , and a model for  $r_x$ , the  $r_x$  are estimated by maximizing the Poisson loglikelihood  $\sum_j [y_j \ln(\mu_j) - \mu_j]$  over the unknown model parameters.<sup>8</sup> The naive estimates in Table 1 were obtained by treating the log HIV rates  $\alpha_x = \ln(r_x)$  as independent parameters. This corresponds to using a saturated log-linear model with an indicator for each year. The backcalculation equation (Eq A1) has no unique solution under this model, but a solution can be obtained by adding a penalty function to the loglikelihood.<sup>8</sup> The penalty function used for Table 1 is  $\sum_x (\hat{\alpha}_x - \bar{\alpha})^2/t^2$ , where  $t^2 = 1.499 \times 10^7$  is the largest value that yielded a solution for Eq A1, and  $\bar{\alpha}$  is the information-weighted average of the current log HIV rate estimates  $\hat{\alpha}_x$ . This penalty produces very mild shrinkage of the year-specific rates toward the weighted mean rate. Note that, counter to intuition, the naive estimates do not average to produce the categorical-model results in Figure 1. This is because the HIV rate estimates for each year are highly nonlinear functions of the AIDS incidence observed in all later years, and these functions differ across models as well as across years.



# Exhibit 155



# Perineal talc use and ovarian cancer risk: a case study of scientific standards in environmental epidemiology

Michael Huncharek<sup>a</sup> and Joshua Muscat<sup>b</sup>

A number of observational studies (largely case-control) conducted over the last two decades suggest an association between use of talc powders on the female perineum and increased risk of ovarian cancer. A subset of these reports shows a roughly 30–60% increased risk of ovarian cancer associated with perineal talc exposure. A number of researchers partly base their conclusions of an association on the ‘...chemical relationship between talc and asbestos’, the latter substance being a known human carcinogen. Although separating causal from noncausal explanations for an observed statistical association is a difficult process, there currently exist commonly accepted guidelines by which such inferences can be made. These scientific approaches include consideration of the strength of the association, the consistency of the finding across studies, and existence of a biological explanation of the observed phenomenon, among others. When applied to the

context of a proposed talc/ovarian cancer association, we conclude that the weak statistical associations observed in a number of epidemiological studies do not support a causal association. *European Journal of Cancer Prevention* 00:000–000 © 2011 Wolters Kluwer Health | Lippincott Williams & Wilkins.

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**Keywords:** causation, cosmetic talc, ovarian neoplasms, risk factors

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## Introduction

Ovarian cancer represents a major cause of cancer-related morbidity and mortality in the United States, with an estimated 22 000 new cases diagnosed in 2005 (Boger-Megiddo and Weiss, 2005). It is the seventh most common cancer in women and ranks fourth as a cause of cancer deaths among females from the United States, with some 16 000 succumbing to the disease this year. The lethality of ovarian tumors is in large part because of the fact that clinical symptoms tend to occur late in the natural history of the disease and the lack of screening tests allowing for early diagnosis. In fact, approximately 60% of patients are diagnosed with late-stage disease (stages III and IV), vastly diminishing the chance of long-term survival [approximately 10% at 5 years from diagnosis (Richardson *et al.*, 1985)].

Primary prevention of ovarian cancer remains elusive as a clear etiology for the vast majority of cases is unknown. In 1982, Cramer *et al.* published the first study suggesting a link between use of cosmetic talc and the risk of developing ovarian cancer. Subsequently, a number of additional reports have shown a small but increased risk among women using cosmetic talc products, although this finding is not universal (Chang and Risch, 1997). These statistical associations raise concerns that a cause–effect relationship may exist between talc exposure (particularly perineal use) and ovarian carcinogenesis.

On 13 May 2008, Samuel Epstein, MD, Chairman of the Cancer Prevention Coalition, submitted a Citizen’s

Petition to the Commissioner of the Food and Drug Administration seeking placement of cancer warning labels on talc products. The Petition requests the Commissioner of Food and Drugs to require that all talc products bear labels with a warning such as, ‘Frequent application of talcum powder in the female genital area substantially increases the risk of ovarian cancer’ (Epstein, 2008).

The claim refers to the first observational study (case–control) suggesting an association between the use of talc powders on the female perineum (by direct dusting or dusting sanitary napkins) and increased risk of ovarian cancer, published in 1982. In this document, the researchers partly base their conclusions of an association on the ‘...chemical relationship between talc and asbestos’, the latter substance being a known human carcinogen. The claim also references a number of additional epidemiological studies conducted after 1982 that have shown a statistical link between talc dusting and ovarian cancer risk. A subset of these reports show a roughly 30–60% increased risk of ovarian cancer associated with perineal talc exposure.

The issues articulated by Epstein *et al.* in relation to the possible carcinogenicity of talc are not uncommon when dealing with interpretation of results derived from observational studies. In a study published 20 years ago, Feinstein provided an insightful and cogent explanation for the myriad problems that plague the process of causal inference as it applies to nonexperimental data (Feinstein, 1988). As he



points out, most people learn about science by studying experimental methods. These methods largely include direct intervention by the experimenter on whatever entity is under study, whether it be an animal species such as rats or mice, specific chemical compounds, subatomic particles, etc. The scientist, in this context, directly manipulates the study subject/object using established principles of experimental science. In the context of human studies, the experimental design that has come to represent the 'gold standard' of cause-effect relationships is the randomized clinical trial. Unfortunately, in epidemiological research, issues of feasibility and ethical considerations preclude randomization of healthy human participants to receive potentially harmful exposures to various substances, including those that represent possible carcinogenic hazards. Therefore, the epidemiologist must substitute observational methods to study cause-effect relationships that preclude direct intervention with, and/or manipulation of, study participants (i.e. experiments). Owing to this fact, criteria for establishing cause-effect relationships are inherently different when using epidemiological methods versus experimental ones.

In 1965, Hill published a landmark study articulating standards for drawing causal inferences from observational data. His rationale for this stemmed from the realization that the urgency of many public health problems demands action despite the fact that existing knowledge might be imperfect (Rothman, 1986). The 'Hill Criteria' as they have become known, are not simply a 'checklist' of requirements that must be met in order to determine cause-effect relationships. Rather, they represent a theoretical framework to guide one's thinking when attempting to decide whether a body of data meets a basic threshold necessary to distinguish causal from noncausal associations. These criteria include: (i) strength of association, (ii) consistency (i.e. repeated observation of an association in different populations under different circumstances), (iii) specificity (a given cause leads to a specific effect), (iv) temporality (cause must precede effect), (v) biological gradient (dose-response), (vi) plausibility (biological plausibility), (vii) coherence (i.e. that a given cause-effect relationship for an association does not conflict with what is known of the natural history and biology of the disease in question), (viii) experimental evidence (to support the observational findings), and (ix) analogy.

Although the Hill criteria do not provide a complete solution to the dilemma of causal inference in epidemiology, their importance lies in establishing at least a general framework for the process. The proposed talc/ovarian cancer association represents an illustrative example of the utility of this framework. Below we discuss the points raised by Epstein *et al.* in this context and show that the conclusion that the proposed talc/ovarian cancer association is causal is not supported by existing data.

### Talc and ovarian cancer: overview of the scientific evidence

The possibility that perineal talc exposure could be associated with development of ovarian cancer was initially derived from a case-control study published in 1982 (Cramer *et al.*, 1982). Since that time, a number of additional reports have addressed this question, with most showing odds ratios (OR) ranging between 1.0 and 2.0 (Table 1). Although this has prompted some to suggest that these estimates of effect provide support for a cause-effect relationship between this exposure and disease outcome, several important caveats must be considered.

Effects of this magnitude are often characterized as 'weak effects' and although the exact definition of a weak effect is debatable, most epidemiologists would consider associations of less than 2.0 to fall within this general category. Hill and others argue that strong associations are more likely to be causal than weak associations as, '...if they were due to confounding or some other bias, the biasing association would have to be even stronger and would therefore presumably be evident' (Rothman, 1986). As Rothman points out, weak associations are more likely to be explained by undetected biases.

Measures of association of this magnitude are often difficult to interpret. This is based on the fact that the investigator cannot directly manipulate the levels of exposure of interest or extraneous factors that could affect study findings. Attempts to control for external factors are accomplished by statistical manipulations of collected data. However, this process depends on the accuracy and completeness of data collection. Further, the correct choice and interpretation of both statistical models and statistical findings can also be contentious.

It is important to point out that although an association is weak, this does not rule out a causal connection. Nonetheless an example of a factor that could confound the weak effect shown for perineal talc is smoking. It is now recognized that smoking is a risk factor for a number of solid tumors including lung cancer (with ORs on the order of 5.0 vs nonsmokers) and esophageal cancer. Evidence exists that smoking may also be related to at least some types of ovarian tumor, in particular those of the mucinous histology (Huncharek *et al.*, in press). The current literature contains a number of reports showing a doubling or tripling of mucinous ovarian cancer risk among smokers (Green *et al.*, 1997; Pan *et al.*, 2004). Interestingly, in a recent meta-analysis of observational studies, Huncharek *et al.* (in press) show that smoking not only increases the risk of mucinous ovarian tumors, but also the more common serous tumors (Table 2). As Rosenblatt *et al.* (1998) reported that smokers are more likely to engage in perineal talc dusting compared with nonsmokers, an imbalance in smokers across case and control groups in epidemiological studies of the talc/ovarian cancer association could contribute to a spurious positive association.



**Table 1 Overview of observational studies examining perineal talc use/ovarian cancer risk**

Reference	Number of cases	Number of controls	Frequency of powder use	OR (95% CI)	Hospital vs. population based study
Booth <i>et al.</i> (1989)	235	451	Never vs. ever	1.29 (0.92–1.80)	H
Chang and Risch (1997)	450	564	None vs. any	1.42 (1.08–1.86)	P
Chen <i>et al.</i> (1992)	112	224	Never vs. ever	3.9 (0.9–10.6)	P
Cook <i>et al.</i> (1997)	313	422	None vs. any	1.5 (1.1–2.0)	P
Cramer <i>et al.</i> (1999)	563	523	Never vs. any	1.60 (1.18–2.15)	P
Cramer <i>et al.</i> (2005)	215	215	None vs. any	1.92 (1.27–2.89)	P
Gertig <i>et al.</i> (2000) <sup>a</sup>	307		Never vs. ever	1.05 (0.84–1.32)	P
Godard <i>et al.</i> (1998)	170	170	Never vs. ever	2.49 (0.94–6.58)	P
Harlow <i>et al.</i> (1992)	235	239	Never vs. any	1.5 (1.0–2.1)	P
Harlow <i>et al.</i> (1992)	116	158	None vs. any	1.1 (0.7–2.1)	P
Ness and Cottreau (1999)	767	158	None vs. any	1.5 (1.1–2.0)	P
Purdie <i>et al.</i> (1995)	824	860	Never vs. ever	1.27 (1.04–1.54)	P
Rosenblatt <i>et al.</i> (1998)	77	46	Never vs. any	1.0 (0.2–4.0)	H
Tzonou <i>et al.</i> (1993)	189	200	Never vs. any	1.05 (0.28–3.98)	H
Whittemore <i>et al.</i> (1998)	188	539	Never vs. ever	1.45 (0.81–2.60)	H
Wong <i>et al.</i> (1999)	499	755	Never vs. ever	1.0 (0.8–1.3)	H

CI, confidence interval; H, hospital-based study; OR, odds ratio; P, population-based study.

<sup>a</sup>Cohort study.

**Table 2 Summary of meta-analysis results**

Risk category	Number of studies	RRs	Statistically homogeneous?
Current/ever smoker	Three cohorts	1.14 (0.93–1.35)	Yes
Current/ever smoker	20 case-control	1.06 (1.01–1.12)	No
Highest vs. lowest pk/years	10 studies (three cohort, seven case-control)	1.21 (1.10–1.31)	No
As above, excluding three studies that combined both borderline and invasive tumors	Seven studies total	1.11 (1.00–1.22)	Yes
Analysis stratified by tumor histology			
Serous tumors			
Current/ever smoker	Four studies	1.28 (0.95–1.61)	Yes
Serous/nonmucinous/other histologies			
Current/ever smoker	Six studies	1.31 (1.15–1.47)	Yes
Mucinous tumors			
Current/ever smoker	Six studies	2.58 (2.23–2.93)	Yes

Pk/years, packs smoked per year; RRs, summary relative risk.

Consistency of an effect could contribute to a causal claim despite a finding of a weak association. Epstein *et al.* characterize the talc/ovarian cancer relationship as being ‘confirmed’ by multiple scientific publications as well as by review of available evidence by the International Agency for Research on Cancer. They state that, ‘...International Agency for Research on Cancer concluded that eight publications confirmed a 30–60% increased risk of ovarian cancer following the perineal application of talc’. Despite the claims of the petitioners, a review of available evidence shows that the epidemiological evidence is not consistent across studies or across study types. For instance, Table 1 shows several inconsistencies in the database. Clearly, not all studies showed a positive, statistically significant association, even among the case-control studies that make up the bulk of the database. In addition, there was relatively wide variation in the magnitude of measures of association.

Interestingly, up to the date of filing of the petition by Epstein *et al.*, only one cohort study had been published, that of Gertig *et al.* (2000) that showed no association between perineal talc use and ovarian cancer risk. Given

the conflicting findings of case-control studies, Huncharek *et al.* (2003) used meta-analytic techniques to explore possible sources of variability among these reports. Their rationale for doing so was that if meta-analyses showed that the patterns of low relative risks or ORs are consistent across all relevant studies in different populations, these weak associations are less likely to be due to confounding or other biases. If a statistical test for heterogeneity shows effects of different magnitudes across studies, sensitivity analyses can be employed to determine the source of observed variability and thereby identify biases due to study design, case-control selection, etc.

Huncharek *et al.* initially pooled data from 15 case-control and one cohort analysis, yielding a summary relative risk (RRs) of 1.33 (1.16–1.45). Although this suggests a statistically significant positive association between perineal talc use and ovarian cancer risk, sensitivity analyses demonstrated clear differences in outcome based on study design. That is, hospital-based case-control studies showed no evidence of an effect [1.19 (0.99–1.41)] in contrast to those reports using population-derived controls [1.38 (1.25–1.52)]. More frequent talc use among hospital-based



control participants versus population-derived controls does not explain this finding, as the proportion of controls using talc was the same in both groups, that is, 32%. Other factors account for this difference in outcome. These findings suggest bias and bring the validity of the initial pooled RRs into question. The Huncharek report provides some possible explanation for the observed differences and indicates that study outcomes are not consistent. It is possible that the potentially spurious positive association between talc use and ovarian cancer risk is the existence of a 'treatment effect' among cases. Particularly among population-based studies, a varying proportion of cases will be prevalent rather than incident. Some patients with ovarian cancer will undergo treatment with radiation, chemotherapy, and/or surgery. Side effects from treatment may prompt talc use among some patients. Although many questionnaires used in case-control studies may specify talc use before diagnosis, patients may not always make the distinction between prediagnosis and posttreatment use. Exposure misclassification among 'prevalent' cases may cause a spurious finding of an association when none, in fact, exists.

Further supporting the findings of this meta-analysis are the more recent and updated pooled data provided by Langseth *et al.* (2008) cited by the Epstein petition. These researchers pooled data from 20 relevant epidemiological studies. Again, although the calculated summary RR obtained from pooling data from all 20 reports gives a statistically significant RRs (pooled odds ratio) of 1.35 (1.26–1.46), the statistical test for data heterogeneity yielded a *P* value of 0.036. A *P* value of this size (i.e. < 0.10) is indicative of significant heterogeneity and, as per convention (Petitti, 2000), precludes statistical pooling, that is the pooled summary estimate of effect is not valid given that the data are heterogeneous. This shows that the available data are not consistent and therefore makes a causal association less likely.

One of the more persistent findings among the epidemiological studies examining this suspected association is the lack of a dose-response relationship. Table 3, derived from data presented in the meta-analysis by Huncharek *et al.*, displays dose-response data for those included studies providing such information. Many of the reports do not show increased risk with increasing exposure. The even more problematic finding in terms of establishing a causal association is that a number of studies suggest that risk decreases with increased exposure (Huncharek *et al.*, 2003).

Few researchers directly address the above-noted lack of evidence of a dose-response relationship. Huncharek *et al.* (2003) and Huncharek and Muscat (2007), in contrast, offer a number of possible explanations for an inverse dose-response relationship. As outlined above, treatment for ovarian cancer may induce specific symptoms that could prompt short-term talc use. For instance, some early stage patients may undergo radiation therapy, which

**Table 3 Talc dose-response data for perineal application and ovarian cancer risk**

Reference	Years of talc use/ OR + 95% CI	Number of talc applications per month/OR + 95% CI
Booth <i>et al.</i> (1989)	NG	1 0.7 (0.3–1.8) 4 2.0 (1.3–3.4) 30 1.3 (0.8–1.9)
Chang and Risch (1997)	<30 1.7 (1.09–2.68) 30–40 1.44 (0.96–2.15) >40 0.96 (0.54–1.38)	<10 1.84 (1.24–2.73) 10–25 1.13 (0.74–1.72) >25 0.95 (0.61–1.49)
Cook <i>et al.</i> (1997)	0–5.5 1.8 (0.9–3.5) 5.5–13.5 1.6 (0.9–2.9) 13.5–27 1.2 (0.6–3.4) >27 1.8 (0.9–3.4)	NG NG NG
Cramer <i>et al.</i> (1999)	<20 1.9 (1.2–3.0) 20–30 1.3 (0.8–2.3) >30 1.4 (0.9–2.3)	<30 2.2 (1.4–3.6) 30–39 1.2 (0.81.8) 40+ 1.6 (0.8–3.1)
Gertig <i>et al.</i> (2000)	NG	4–24 0.99 (0.67–1.46) ≥ 30 1.12 (0.82–1.55) <5 1.5 (0.8–2.7)
Harlow <i>et al.</i> (1992)	<10 1.2 (0.5–2.6) 10–29 1.6 (1.0–2.7) ≥ 30 1.6 (1.0–2.7)	5–29 1.2 (0.6–2.2) ≥ 30 1.8 (1.1–3.0) NG
Ness and Cottreau (1999)	1 2.0 (1.0–4.0) 1–4 1.6 (1.1–2.3) 5–9 1.2 (0.8–1.9) 10+ 1.2 (1.0–1.5)	1–20 1.27 (0.82–1.96)
Whittemore <i>et al.</i> (1998)	1–9 1.60 (1.00–2.57) 10+ 1.11 (0.74–1.65)	>20 1.45 (0.94–2.22) NG
Wong <i>et al.</i> (1999)	1–9 0.9 (0.6–1.5) 10–19 1.11 (0.74–1.65) ≥ 20 0.9 (0.6–1.2)	NG

CI, confidence interval; NG, not given; OR, odds ratio.

causes skin irritation. Such side effects could result in some patients using talc products to address these side effects. Talc is often recommended to keep skin folds in the perineum dry and prevent skin breakdown secondary to radiation. In addition, symptoms of the disease process itself could cause some women to use talc to counter these symptoms. Paulsen *et al.* (2005) and Golf *et al.* (2004) document that a number of symptoms are quite common among ovarian cancer cases versus control participants. For instance, Golf *et al.* show that increased abdominal size is over seven times more common among cases versus controls, whereas abdominal bloating is 2.5 times more common. The combination of bloating, increased abdominal size and urinary symptoms were found in almost half of all patients with ovarian cancer, but in only 8% of controls. In addition, of interest are the findings by Green *et al.* (1997) that increased ovarian cancer risk was seen among patients with painful periods or excessive vaginal bleeding. Again, such symptoms could prompt talc use and lead to a spurious association with talc. Although there are no firm data in the existing literature to definitively establish that these factors lead to increased short-term use of talc, the scenarios are



plausible and could explain the inverse dose–response relationship seen in a number of epidemiological studies.

The majority of reports largely ignore the counterintuitive findings, although Cramer *et al.* (1999) attribute the dose–response inconsistencies, possibly to the ‘crudeness’ of the exposure measurement used. What is not acknowledged is that this same problem of imprecise exposure estimates could also explain a spurious positive association of talc and ovarian cancer, especially in light of the inconsistent outcomes across reports. In summary, the failure to show a coherent and consistent relationship between talc exposure and ovarian cancer risk argues against a causal association.

An additional limitation of the existing literature dealing with the proposed talc/ovarian cancer association is the lack of any known biological mechanism through which talc particles could induce ovarian tumors. This represents probably the most troublesome aspect of arguments in support of this proposed causal association. It is also interesting to note that biological theories put forth to explain how talc may cause neoplastic transformation have changed over time as various proposed mechanisms have met with criticism in the developing literature.

Initially, Cramer *et al.* (1982) and others sought to draw an analogy between talc and fibrous asbestos, the latter being a known and well-described carcinogen. The biological effects of asbestos have been elucidated over the last 50–60 years by a multitude of epidemiological, in-vitro and in-vivo studies (Huncharek, 1986). Specific asbestos types are recognized as both animal and human carcinogens and, because of this fact, this commodity is banned from use in the United States.

A number of investigators initially implicated talc products as possible carcinogens, as before the early 1970s some talc products contained small amounts of asbestos fibers (Rohl *et al.*, 1976). Clearly, such products could possibly represent a carcinogenic risk secondary to the asbestos contamination. It should be pointed out that this in no way implicates talc as a toxin as the problematic constituent of such products was the asbestos fibers, not talc.

Since the early 1970s, the relevant industries voluntarily eliminated asbestos contamination from talc products. On account of this, the ‘antitalc’ argument shifted to implicate talc itself as a carcinogenic risk based on its ‘chemical similarity’ to asbestos. It is interesting, and confusing, as to why talc is thought by some to be carcinogenic based on the fact that there are some common chemical constituents of talc and asbestos.

Both commercial talc and the group of minerals known as asbestos are magnesium silicates. Beyond that fact, the two substances share no common characteristics. The work by Stanton *et al.* (1981) shows that the carcinogenic ability of fibrous asbestos is due to its structure, not its

chemical composition. Although talc and asbestos are both magnesium silicates, they are structurally distinct and belong to different mineral groups and subgroups, as detailed by Muscat and Huncharek (2008). Amphibole asbestos minerals are inosilicates while talc is a member of the silicate subclass phyllosilicate and group clay or montmorillonite/smectite. Although serpentines, including serpentine asbestos (chrysotile), are also phyllosilicates, serpentine minerals belong to the kalolinite–serpentine group. The asbestos varieties of serpentine are structurally different from other members of the serpentines in that their brucite layers and silicate layers bend into tubes that produce fibers. Nonfibrous serpentine does not have carcinogenic properties and it is clear that the physical structure of serpentine asbestos (and amphibole asbestos) is responsible for its disease-causing potential, not its atomic constituents. It simply does not follow that one should assume talc is carcinogenic simply because it is a silicate. Structure, not chemical composition, dictates toxicity/carcinogenicity.

Given the dissimilarities between talc and asbestos with regard to their fibrous shapes, the weak but increased associations in the epidemiological studies could be attributed to other mechanisms, assuming that the statistical associations are unbiased and not due to confounding. Asbestos fibers in the lung initiate an inflammatory and scarring process, and it has been proposed that ground talc, as a foreign body, might initiate an inflammatory response (Ness and Cottreau, 1999). Pelvic inflammatory diseases, however, such as endometriosis, peritonitis, tuboovarian abscess formation, etc., have not been associated with an increased risk of ovarian cancer. A meta-analysis of studies of antiinflammatory drug use found no reduction in ovarian cancer risk (Bonovas *et al.*, 2005). In fact, the study by Merritt *et al.* (2008) that was cited by Epstein *et al.* also showed no relationship between inflammation and ovarian cancer risk.

Most recently, Cramer *et al.* (2005) proposed that the talc/ovarian cancer association might be explained by the induction of anti-MUC1 antibodies. This idea has been debated on statistical grounds in which talcum powder applied to the perineum was associated with increased anti-MUC1 expression but the correlation was also observed when talc powder was applied to other body parts. More importantly, the simple observation that talc elevates immunoglobulin protein levels in blood, possibly by heat shock proteins, seems to have no known direct relevance for ovarian cancer, as anti-MUC1 is associated with other cancers and because there is no known role of heat shock proteins in ovarian cancer risk.

Some of the most important biological data supporting the nontoxic nature of talc come from the clinical use of talc in treating both malignant and benign pleural effusions in humans (i.e. pleurodesis). This is a common procedure in the United States and elsewhere and talc



slurry is applied directly to the pleura (through chest tube placement) to induce obliteration of the pleural space by scarring and prevent the reaccumulation of fluid secondary to tumor or benign causes. Multiple long-term clinical studies, as reviewed by Muscat and Huncharek (2008), have not shown a single case of cancer secondary to direct talc application to the human pleura (Shaw and Agarwal, 2004). There are also data showing that talc has demonstrated antitumor properties secondary to the induction of endostatin when used in pleurodesis (Najmunnisa *et al.*, 2007). In fact, patients with pleurodesis treated with talc are known to experience longer survival times than those treated with other sclerosing agents. This is likely due to the tumor-inhibitory effects of talc.

Finally, other human data, such as the demonstration that talc inhaled in mining and milling operations is not associated with increased pulmonary tumors, and the likelihood that talc could selectively induce ovarian cancer and not lung cancer at exposure concentrations orders of magnitude lower than that experienced in occupational settings, argue against its toxicity (Muscat and Huncharek, 2008).

Although the process of drawing causal inferences from scientific data is complex, application of accepted standards, as noted above, to the talc/ovarian cancer relationship clearly indicates that the available epidemiological and other evidence does not support a causal connection. The weak association shown in a subset of observational studies can potentially be explained by numerous alternative hypotheses, as detailed throughout this document. Given the lack of supporting evidence from in-vivo, in-vitro, and clinical research studies using human participants, the weak epidemiological association is unlikely to be causal.

## Summary

Although separating causal from noncausal explanations for an observed statistical association is a difficult process, there currently exist commonly accepted guidelines by which such inferences can be made. These scientific approaches include consideration of the strength of the association, the consistency of the finding across studies, and existence of a biological explanation of the observed phenomenon, among others. When applied to the context of a proposed talc/ovarian cancer association, we conclude that the weak statistical associations cited in the petition do not support a causal association.

These conclusions are based on a number of statistical, methodological, and biological issues. First, contrary to the assertions of Epstein (2008), findings from the cited studies are not consistent from study to study, and also differ by study design. Two meta-analyses by Huncharek *et al.* (2003) and Langseth *et al.* (2008) both show significant differences in summary ORs between popula-

tion-based and hospital-based case-control studies, with the latter showing generally null results. The Nurses Health Study, the one prospective study that examined this association, found no risk with talc dusting. Formal statistical tests for heterogeneity in both analyses support this finding. This fact suggests the existence of bias, and standard approaches to meta-analysis indicate that the pooled OR, in this case an OR of 1.30, is not valid in the presence of heterogeneity. Huncharek and Muscat (2007) suggest multiple possible sources of bias that could produce a spurious positive finding, including unaccounted for effects of cancer treatment and confounding by smoking.

The assembled data also fail to show a clear dose-response relationship, that is, increasing ovarian cancer risk with increasing talc exposure. Some epidemiological studies actually suggest an inverse association between perineal talc exposure and cancer risk. The reasons for this inverse association in some studies are not known, but could be due to aspects of talc usage that are not fully understood such as the possibility that disease symptoms or cancer treatment may spur temporary talc use in case patients.

There is no coherent biological explanation as to how talc could induce cancer of the ovary. The theories put forth to explain the statistical association between talc and ovarian cancer have changed over time with little underlying consistency. The long-standing claim that talc is chemically 'similar' to asbestos and is therefore a carcinogen is a misunderstanding of the chemical and physical properties of talc.

The use of therapeutic talc for pleurodesis in patients with benign and malignant pleural effusions involves the direct application of talc to the human pleura. Clinical follow-up studies of these patients have shown no increased incidence of lung or pleural malignancies despite patient follow-up extending over decades. The above-noted data are supported by the lack of positive findings among occupational cohorts exposed to talc, and negative findings from various animal studies. More recently proposed mechanisms based on other biological pathways are speculative at this point. Given the lack of supporting evidence from in-vivo and clinical research studies using human participants, the weak and inconsistent epidemiological associations, that also lack a gradient in effect, argue against a claim of causality.

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# Exhibit 156





July 21, 2009

Division of Dockets Management  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

**RE: Comments on: Citizens Petition to the Commissioner of the Food and Drug Administration Seeking a Cancer Warning on Talc Products**  
**Docket FDA-2008-P-0309**

Dear Division of Dockets Management:

The Personal Care Products Council<sup>1</sup> (the Council) appreciates the opportunity to comment on the above referenced Citizens Petition. Cosmetic talc is used within the personal care products industry, and thus, the request for a warning is of significant interest to the Council's members.

A 1994 Citizen's Petition to FDA similarly requested that FDA (1) immediately require cosmetic talcum powder products to bear labels with a warning such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital area increases the risk of ovarian cancer" and (2) hold a hearing to allow the petitioner to present scientific evidence to support their petition. FDA did not act on this petition and did not implement the requests made by the petitioner. We believe the current request for a cancer warning also lacks scientific merit, and that a review of all of the pertinent literature supports our confidence in the safety of cosmetic talc.

The 2008 Petition cites twelve articles that are described as 'confirming' "the causal relation between genital application of talc and ovarian cancer." We disagree with the petitioner's interpretation of the data that are cited, and we believe that the available ovarian cancer epidemiology studies do not support a causative role for talc. We note that ~half of the citations

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<sup>1</sup> Based in Washington, D.C., the Personal Care Products Council (formerly CTFA) is the leading national trade association representing the \$250 billion global cosmetic and personal care products industry. Founded in 1894, the Council's more than 600 member companies manufacture, distribute, and supply the vast majority of finished personal care products marketed in the United States. As the makers of a diverse range of products millions of consumers rely on everyday, from sunscreens, toothpaste and shampoo to moisturizer, lipstick and fragrance, personal care products companies are global leaders committed to product safety, quality and innovation.





do not provide new data on talc and ovarian cancer, but rather are reviews of data on ovarian cancer incidence in general.

To address these issues further, the Council hereby submits a detailed review of the points raised in the petition, co-authored by Dr. Michael Huncharek, MD, MPH, Meta-Analysis Research Group and Associate Professor of Preventive Medicine, University of South Carolina School of Medicine, Columbia, SC; and Dr. Joshua Muscat, Ph.D., MPH, Meta-Analysis Research Group and Professor of Public Health Sciences, Pennsylvania State University College of Medicine, Hershey, PA. The review includes an assessment of each of the twelve literature references cited in the petition, with an assessment of the relevance of the study findings to support a causal association (Attachment).

This review concludes that “the weak epidemiological association is unlikely to be causal.” Arguing against a causal association are lack of a clear dose-response relationship between increasing talc exposure and increasing ovarian cancer risk, with some epidemiological studies suggesting an inverse association between exposure and risk. A plausible biological mechanism is lacking to explain a causal relationship. The finding of a small increase in relative risk could be due to several potential confounding factors. A serious limitation of the epidemiology studies, many of which were not specifically designed to test the hypothesis that talc use contributes to ovarian cancer, is that the true exposure of ovarian tissue to talc is by necessity unknown, and can only be poorly estimated using proxy measures (i.e., self-reporting of talc use in the perineal area).

Given the lack of evidence of a causal role for talc in ovarian cancer, we therefore respectfully ask that the Petitioners’ request for a cancer warning be denied. The basis of the request lacks scientific merit and the addition of a warning label would be inappropriate and unnecessarily alarming.

Thank you for the opportunity to comment on the Citizens Petition. Please let us know if we can provide more information.

Sincerely,

A handwritten signature in black ink, appearing to read "John E. Bailey". The signature is fluid and cursive, with the first name "John" being more prominent than the last name "Bailey".

John E. Bailey, Ph.D.  
Executive Vice President – Science



## ATTACHMENT





**Comments on: Citizens Petition to the Commissioner of the Food and Drug  
Administration Seeking a Cancer Warning on Talc Products**

Prepared by

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and  
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Washington DC



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## **I. Introduction**

On May 13, 2008, Samuel Epstein, MD, Chairman of the Cancer Prevention Coalition, submitted a Citizen's Petition to the Commissioner of the Food and Drug Administration seeking placement of cancer warning labels on talc products. The Petition requests the Commissioner of Food and Drugs to require that all talc products bear labels with a warning such as, "Frequent application of talcum powder in the female genital area substantially increases the risk of ovarian cancer."

Given the multiple implications of such warning labels, The Personal Care Product Council sought an evaluation of the validity of the scientific facts underlying this request. The Meta-Analysis Research Group was retained to provide an independent review of the relevant data. Below are the findings of this review.

## **II. Executive Summary**

This document is in response to the recent Citizens Petition to the Food and Drug Administration (FDA) that seeks placement of a cancer warning on cosmetic talc products (2008). Dr. Samuel Epstein, Chairman of the Cancer Prevention Coalition, and other interested parties, filed this petition.

The claim refers to the first observational study (case-control) suggesting an association between use of talc powders on the female perineum (via direct dusting or dusting sanitary napkins) and increased risk of ovarian cancer, published in 1982. In this document, the authors partly base their conclusions of an association on the "...chemical relationship between talc and asbestos", the latter substance being a known human carcinogen. The claim also references a number of additional epidemiological studies conducted after 1982 that have shown a statistical link between talc dusting and ovarian cancer risk. A subset of these reports show a roughly 30-60% increased risk of ovarian cancer associated with perineal talc exposure.

Although separating causal from non-causal explanations for an observed statistical association is a difficult process, there currently exist commonly accepted guidelines by which such inferences can be made (see Hill, 1965). These scientific approaches include consideration of the strength of the association, the consistency of the finding across studies, and existence of a biological explanation of the observed phenomenon, among others. When applied to the context of a proposed talc/ovarian cancer association, we conclude that the weak statistical associations cited in the petition do not support a causal association.

Our conclusions are based on a number of statistical, methodological and biological issues. First, contrary to the assertions of Epstein et al., findings from the



cited studies are not consistent from study to study, and also differ by study design. Two meta-analyses by Huncharek et al. (2003) and Langseth et al. (2008) both show significant differences in summary odds ratios between population-based and hospital-based case control studies, with the latter showing generally null results. The Nurses Health Study, the one prospective study that examined this association, found no risk with talc dusting. Formal statistical tests for heterogeneity in both analyses support this finding. This fact suggests the existence of bias and standard approaches to meta-analysis indicate that the pooled odds ratio, in this case an OR of 1.30, is not valid in the presence of heterogeneity. Huncharek et al. (2003, 2007) suggest multiple possible sources of bias that could produce a spurious positive finding, including unaccounted effects of cancer treatment and confounding by smoking.

The assembled data also fail to show a clear dose-response relationship, i.e. increasing ovarian cancer risk with increasing talc exposure. Some epidemiological studies actually suggest an inverse association between perineal talc exposure and cancer risk. The reason for this inverse association in some studies is not known, but could be due to aspects of talc usage that are not fully understood such as the possibility that disease symptoms or cancer treatment may spur temporary talc use in case subjects.

There is no coherent biological explanation as to how talc could induce cancer of the ovary. The theories put forth to explain the statistical association between talc and ovarian cancer have changed over time with little underlying consistency. The long-standing claim that talc is chemically "similar" to asbestos and is therefore a carcinogen is a misunderstanding of the chemical and physical properties of talc.

The use of therapeutic talc for pleurodesis in patients with benign and malignant pleural effusions involves the direct application of talc to the human pleura. Clinical follow-up studies of these patients have shown no increased incidence of lung or pleural malignancies despite patient follow-up extending over decades. The above noted data are supported by the lack of positive findings among occupational cohorts exposed to talc and negative findings from various animal studies. More recently proposed mechanisms based on other biological pathways are speculative at this point. Given the lack of supporting evidence from *in vivo* and clinical research studies using human subjects, the weak and inconsistent epidemiological associations, that also lack a gradient in effect, argues against a claim of causality.



### III. Overview of citations listed in the CPC Petition to the FDA

**Citation: #1**, National Cancer Institute. SEER Cancer Statistics Review, 2005.

#### SUMMARY OF FINDINGS:

The age-adjusted U.S. mortality rate from ovarian cancer in elderly white and black women (ages 65+) increased from 1975-1991, and has remained stable from 1991-2005. In contrast the SEER (Surveillance Epidemiology and End Results Program) incidence rates of ovarian cancer in elderly white women increased from 1975-1991, but has decreased since that time. In elderly black women the rates have been stable throughout this period. The age-adjusted incidence and mortality rates of younger white and black women (<65) have decreased about 30% from 1975-2005. There is a poorer survival rate among elderly women. (see Appendix re: SEER data)

Ovarian cancer is estimated to be the 5<sup>th</sup> most common form of cancer deaths among women in 2008.

#### ALLEGATIONS OF PETITION'S AUTHORS re: CITATION:

The authors make no claim with regard to talc causality. The data presented are intended to show that ovarian cancer is a relatively common cancer and has a poor prognosis, especially in older women.

#### MEASURE OF RELATIVE RISK/ODDS RATIO:

None.

#### RELEVANCE OF STUDY FINDINGS TO SUPPORT CAUSAL ASSOCIATION:

None. The data cited are intended to show that if talc has an effect, it is an important public health problem given the high case fatality rate from ovarian cancer in older women.

It should be noted that Epstein et al. cited mortality data that do not reflect updated SEER information showing that mortality for this disease has been stable for almost the last two decades. In addition, the incidence data show stable or decreasing rates since 1991 with incidence and mortality declining substantially among women under 65 years of age.

**Citation: #2**, Purdie D. et al. Reproductive and other risk factors and risk of epithelial ovarian cancer : An Australian case-control study. Survey of Women's Health Study Group. Int J Cancer 1995; 62:678-684.

#### SUMMARY OF FINDINGS:



Purdie conducted a population-based case-control study of 824 histologically confirmed cases and 860 controls in Australia. No response rate was given but it appears that a large number of cases could not be located or agree to be interviewed post-diagnostically. There may have been a survivor effect where the enrolled cases were more likely to have been early stage cases. This study was done to assess hormonal/reproductive factors on ovarian cancer risk. There was one question asked on talc exposure.

ALLEGATIONS OF PETITION'S AUTHORS re: CITATION:

The petition authors cite this reference as "confirming" the findings of prior work showing a positive relationship between perineal talc use and ovarian cancer risk.

MEASURE OF RELATIVE RISK/ODDS RATIO:

The "use of talc around abdomen/perineum" was associated with a nonsignificant 1.21 [1.00-1.46] risk and a significant 1.27 [1.04-1.54] risk in nulliparous women.

RELEVANCE OF STUDY FINDINGS TO SUPPORT CAUSAL ASSOCIATION:

The question of statistical significance is ambiguous here. The crude odds ratio is nonsignificant or of borderline significance and not adjusted for confounders. The authors calculated an adjusted odds ratio in only a subset of women (e.g. nulliparous) women because the overall study was designed to examine hormonal factors, and the sample size was large enough to conduct a stratum-specific analysis to remove the confounding effects of parity. However, since talc was clearly not the main hypothesis, the adjusted odds ratio in only a subset of women makes it difficult to interpret and generalize the talc findings. Thus it may be argued that the nonsignificant crude odds ratio is the more appropriate measure. While the difference in the crude and the adjusted subsetted OR is quite small, such differences become important given that the overall "effect" of talc exposure in this study and the literature in general is small to begin with. The meta-analysis by Huncharek et al. included the adjusted odds ratio, but in retrospect the lower crude OR was probably the better measure when pooling the results. There are no data on dose-exposure response effect or latency. The association with talc cannot be considered causal in this individual study as the exposure is crudely defined, the findings based on the whole dataset are marginally significant, and there are no dose-response data.

**Citation: #3, Kasper CS, Chandler PJ Jr. Possible morbidity in women from talc on condoms [letter]. JAMA 1995; 846-847.**

SUMMARY OF FINDINGS:



This is an article that raises the hypothesis that talc on condoms and diaphragms may cause ovarian cancer. The original hypothesis that talc used on birth control devices may be associated with disease risk was raised in 1979 by Longo and Young (Lancet 1979;2:349-351). Kasper cites new microscopy data that supports this hypothesis, with findings demonstrating the presence of talc on condoms, with varying degrees of density/surface area depending on the brand.

ALLEGATIONS OF PETITION'S AUTHORS re: CITATION:

The petition authors cite this reference as "confirming" the findings of prior work showing a positive relationship between perineal talc use and ovarian cancer risk.

MEASURE OF RELATIVE RISK/ODDS RATIO:

None.

RELEVANCE OF STUDY FINDINGS TO SUPPORT CAUSAL ASSOCIATION:

There is no new data that confirms that talc is associated with ovarian cancer. Rather, the hypothesis that talc from other sources besides perineal dusting, is alleged to possibly cause ovarian cancer. The documentation that talc is found to be concentrated on the surface of latex condoms raises the hypothesis that condom use may cause ovarian cancer.

Kasper hypothesizes that with the large increase of condom use in the U.S. from 1985-1995, that if talc were carcinogenic to the ovaries there would be a large increase in the rates of ovarian cancer in the U.S. We previously examined the rates of ovarian cancer to determine if there have been any increases in incidence during this time period. We found no evidence for an increased SEER rate (Muscat and Huncharek. Eur J Cancer Prev. 2008;17:139-46). Using the latest data from the SEER program, it can be seen that the age-adjusted incidence rates for ovarian cancer in white women have declined by about 20% since 1985, the date of the Kasper article. These data clearly do not support the Kasper hypothesis and the claim made by Dr. Epstein and others.

**Citation: #4, Cramer DW & Xu H. Epidemiologic evidence for uterine growth factors in the pathogenesis of ovarian cancer. Am J Epidemiol 1995; 5:310-314.**

SUMMARY OF FINDINGS:

This was a hospital-based case-control study from two time periods that included a total of 450 cases and 454 controls from Boston. The controls were randomly selected women from the population. Controls with a history of bilateral oophorectomy were excluded.

MEASURE OF RELATIVE RISK/ODDS RATIO:



"Talc use for genital hygiene" was associated with a crude 1.6 [1.2-2.1] risk.

ALLEGATIONS OF PETITION'S AUTHORS re: CITATION:

The authors cite Cramer 'confirming' the results from Purdie.

RELEVANCE OF STUDY FINDINGS TO SUPPORT CAUSAL ASSOCIATION:

It is not clear if the OR presented is the crude or adjusted odds ratio. A calculation of the crude OR from the table reveals a 1.6 odds ratio. The table (Table 1) does not indicate that the OR is adjusted despite the methods section stating that adjustments were made. In contrast tables 2 and 4 had footnotes indicating the OR for other risk factors were adjusted ORs. There were no dose-response data provided.

Use of body powders was assessed via personal interview. Use of powder in non-genital areas was not associated with increased ovarian cancer risk (1.08[0.77-1.50]) nor was increased risk seen among those using powder to dust the perineum (1.45[0.97-2.18]), dusting sanitary napkins (1.45[0.68-3.09]) or dusting underwear 1.21[0.40-3.64]). An elevated risk of ovarian cancer was noted for the exposure categories "multiple uses, genital area", i.e. 2.15(1.30-3.57) and "any personal genital exposure", i.e. 1.6(1.18-2.15).

Only one case and three controls reported using cornstarch powders. Dose-response analysis showed an inverse relationship for both frequency of use per month or number of applications.

The authors conclude that there is a "significant association between the use of talc in genital hygiene and risk of epithelial ovarian cancer."

ALLEGATIONS OF PETITION'S AUTHORS re: CITATION:

The authors cite Cramer et al. to document that these investigators suggested institution of "formal public health warnings" in 1999 based on their interpretation of existing data, i.e. that they "confirm" the relationship between perineal talc use and ovarian cancer is causal.

MEASURE OF RELATIVE RISK/ODDS RATIO:

Risk associated with genital exposure to talc, OR=1.60(1.18-2.15)

RELEVANCE OF STUDY FINDINGS TO SUPPORT CAUSAL ASSOCIATION:

This population-based case-control study found a statistically significant association between "any personal genital exposure" to talc and risk of ovarian cancer with an odds ratio of 1.60(1.18-2.15). No clear dose-response relationship was seen. In fact, data in both tables II and III suggest an inverse dose-response.



**Citation: #5,** Chang et al. Perineal talc exposure and risk of ovarian carcinoma. Cancer 79:2396-2401, 1997.

**SUMMARY OF FINDINGS:**

Chang and Risch present the findings of a population based case-control study of ovarian cancer risk associated with perineal exposure to talc. The study population was derived from Ontario, Canada and consisted of 450 cases and 564 controls. Dusting or powdering behaviors considered included regular application of talc to the perineum after showering or bathing and dusting of talc on sanitary napkins. Similar information was recorded regarding use of cornstarch products.

Analyses were adjusted for age, oral contraceptive use, average duration of breastfeeding per pregnancy, tubal ligation/hysterectomy or family history of ovarian or breast cancer. No adjustment was made for smoking history.

Women with any regular talc exposure showed an increased risk of disease, i.e. OR=1.42(1.08-1.86) with no association seen with talc exposure via dusting of sanitary napkins, i.e. OR of 1.26(0.81-1.96). Use after bathing showed a borderline effect of 1.31(1.00-1.73). As noted in a number of other observational studies, no increasing risk of ovarian cancer with increasing talc exposure was noted.

The authors concluded that their data provide support that perineal talc use may increase the risk of ovarian cancer. They acknowledged that the lack of a dose-response needs clarification. In fact, an inverse dose-response is suggested by the data in Table 2 of the manuscript.

**ALLEGATIONS OF PETITION'S AUTHORS re: CITATION:**

Epstein et al. suggest that reference number five supports the findings of Purdie et al. (reference #2), the largest case-control analysis examining perineal talc and ovarian cancer risk as well as other reports cited in the petition.

**MEASURE OF RELATIVE RISK/ODDS RATIO:**

Any perineal talc exposure: OR=1.42(1.08-1.86)  
Dusting of sanitary napkins: OR=1.26(0.81-1.96)  
Talc use after bathing: OR=1.31(1.00-1.73)  
>25months use of after-bath talc: OR=0.95(0.61-1.49)  
>40yrs after bath talc use: OR=0.87(0.54-1.38)

**RELEVANCE OF STUDY FINDINGS TO SUPPORT CAUSAL ASSOCIATION:**

Chang and Risch indicate that their study results "appear to support the contention that talc exposure increases risk of ovarian carcinoma." The Discussion section of the article gives an overview of the literature and addresses some of the limitations of the available database. Although there is some



discussion in the manuscript regarding the dose-response data, Chang and Risch do not provide an explanation for the lack of a dose-response (or inverse response) in their report or others in the literature. This is clearly an important criterion for drawing causal connections so the nature of the dose-response relationship is crucial to interpretation of possible biological relationships.

Chang and Risch also make reference to the fact that asbestos and talc are "chemically related". This is an often-repeated claim in many papers dealing with talc in the medical literature. In our recent publication in the European Journal of Cancer Prevention we describe how there is little mineralogical similarity between talc and asbestos other than both being magnesium silicates (Muscat, Huncharek, 2008). Commercial talc is a soft, non-fibrous entity that is structurally unlike the forms of asbestos associated with malignant disease in humans. There are new scientific findings in this area that demonstrate different carcinogenic effects between talc and asbestos. For example, talc induces apoptosis (programmed cell death) in malignant mesothelioma cells but not in normal mesothelial tissue while asbestos induces programmed cell death in normal mesothelium (see Nasreen et al., 2000 and Broaddus et al., 1996). Talc has also been found to alter the angiogenic balance (blood vessel growth promotion versus blood vessel growth inhibition) in the pleura by inducing the production of endostatin (an inhibitor of blood vessel growth) by normal pleural mesothelial cells but not in malignant mesothelial cells, thereby creating an angiostatic, and therefore, tumor inhibitory environment (see Najmunnisa et al., 2007).

**Citation: #6,** Daly M, Oubram I, Epidemiology and risk assessment for ovarian cancer. Seminar Oncology 1998; 25:

#### SUMMARY OF FINDINGS:

This is a review article on the epidemiology of ovarian cancer. It reviews many risk factors besides talc.

#### ALLEGATIONS OF PETITION'S AUTHORS re: CITATION:

The petition authors cite this reference as "confirming" the findings of prior work showing a positive relationship between perineal talc use and ovarian cancer risk. However, Daly and Oubram did not publish new data, and do not offer an opinion on the causality of the association. Rather they state, "The use of talc in dusting the perineum, in feminine hygiene sprays, or on sanitary napkins, condoms, or diaphragms has been suggested as a possible risk factor for ovarian cancer. " They cite the article by Harlow that shows a 1.5 fold risk and a higher risk in long-term users (> 10 years). The 1982 Cramer article was cited as talc being significantly contaminated with asbestos. They cite the article by Heller et al, that ovarian tissue is contaminated with asbestos and that the fiber burdens were highest in women whose fathers/husbands had a history of asbestos exposure.



MEASURE OF RELATIVE RISK/ODDS RATIO:  
NA

RELEVANCE OF STUDY FINDINGS TO SUPPORT CAUSAL ASSOCIATION:

Daly and Oubram did not publish new data, and state that talc has been investigated "as a possible risk factor" for ovarian cancer. This is clearly not a statement that they believe the association is causal. There is no scientific checklist for determining a causal association. The Hill postulates or variations of the Hill postulates are often used to help make assessments of causality (Hill, 1965). These postulates include strong associations, consistent associations across studies, biological plausibility, dose-response relationships and others.

**Citation:** #7, Green A et al. Tubal sterilization, hysterectomy and decreased risk of ovarian cancer. *Int J Cancer* 71:948-951, 1997.

SUMMARY OF FINDINGS:

Using a population-based case-control study design (with 824 cases), Green et al. examined the effects of tubal sterilization and hysterectomy on ovarian cancer risk. Both procedures were shown to have a protective effect ranging from a 37% to 74% risk reduction. Data on "ever" versus "never" perineal talc use were also available. The analysis showed a "modest" (authors' terminology), but significant, association between perineal talc use and ovarian cancer risk, i.e. 1.3(1.1-1.6). No dose-response was found and the authors acknowledged this fact.

The investigators also collected information on talc exposure via condom and contraceptive diaphragm use. Duration of use for both exposures showed no association with ovarian cancer risk, consistent with others in the literature recently reviewed by Huncharek and Muscat (*European Journal of Cancer Prevention*, 2007). The relevant raw data were not presented in the manuscript nor were odds ratios given for these associations.

Interestingly, women with either heavy or painful periods had a marginally increased risk of ovarian cancer, i.e. 1.2(0.93-1.4), 1.1(0.86-1.4) respectively. The magnitude of effect between these two groups is similar to that seen for perineal talc use in this study. The authors provide no further discussion of this finding. This raises the question as to whether there is any relationship between heavy menstruation/painful periods and talc use. It should be noted that investigators such as Paulsen et al. show that abdominal pain is reported by 53% of women with invasive epithelial ovarian cancer prior to diagnosis (Paulsen, 2005). Among the cohort studied by Paulsen et al., fourteen percent of women with ovarian cancer also reported abnormal vaginal bleeding. It is unclear at present whether these symptoms could prompt talc use, in the short term and contribute to a spurious association with ovarian cancer e.g., detection bias may account for



the talc/ovarian cancer connection due to these factors. Further data are needed to clarify this issue.

ALLEGATIONS OF PETITION'S AUTHORS re: CITATION:

The petition authors cite this reference as "confirming" the findings of prior work showing a positive relationship between perineal talc use and ovarian cancer risk. In the discussion of the paper, the authors reiterate the theory of Cramer et al. that artificial closure of the fallopian tube prevents toxins from traversing the tube and depositing on the ovary, despite the fact that this view is speculative. Nonetheless, the odds ratio of 1.3 is consistent with a number of other observational studies in the literature.

As we will discuss in our report summary, this theory is also challenged by new work suggesting that the origin of serous ovarian tumors, the most common type of ovarian carcinoma, may actually be the distal fallopian tube, i.e. the fimbria (see, for instance Crum CP et al. Clinical Medicine and Research 5(1):35-44, 2007). The decrease in ovarian cancer among women with hysterectomy/tubal ligation could be due to removal of the site of origin rather than obstruction of a physical route of passage for suspected carcinogens. The Crum et al. findings are relatively recent and have not been discussed in the medical literature in the context of the talc/ovarian cancer hypothesis. It is our feeling that this pathological information could represent an important piece of evidence that challenges the biological explanation offered for these epidemiological findings.

MEASURE OF RELATIVE RISK/ODDS RATIO:

Relative risk of perineal talc use, OR=1.3(1.1-1.6).

RELEVANCE OF STUDY FINDINGS TO SUPPORT CAUSAL ASSOCIATION:

The report by Green et al. was designed specifically to examine the impact of hysterectomy and tubal sterilization on ovarian cancer risk rather than the influence of perineal talc exposure. Talc data were collected although the raw data are not presented in the published manuscript. The weak effect shown for talc exposure is presented by the authors as supportive of the theory that interruption of the fallopian tube prevents the passage to carcinogens, including talc, from reaching their target organ, i.e. the ovary. Despite the fact that this theory is put forth in much of the relevant literature, it remains speculative. As noted previously, there does exist pathology literature that suggests the origin of epithelial ovarian tumors is actually the fimbria (distal fallopian tube). Should this be proven to be correct, it would present a challenge to the talc carcinogenesis theory.

The Green et al. data do not show a dose-response relationship with condom or diaphragm use. Other work supports this, as does our recent review in the European Journal of Cancer Prevention (Muscat, Huncharek, 2008). Talc exposure via this route is directly into the female reproductive tract in contrast to



perineal dusting. This persistent finding in the epidemiological literature also argues against the talc/ovarian cancer association being causal.

The Green et al. paper also raises another interesting point. As briefly discussed above, this study shows that women with painful or heavy menstrual periods had a marginally increased risk of ovarian cancer. There is a body of literature that documents the occurrence and nature and frequency of symptoms, including these, among patients with epithelial ovarian cancer. Compared with controls, ovarian cancer patients report a multitude of symptoms including pain, abdominal bloating and urinary frequency. In addition, some of this work provides information on the duration of these symptoms prior to diagnosis, ranging from weeks to many months. These factors could contribute to a detection bias where ovarian cancer symptoms could prompt short-term talc use. Although this suggestion is theoretically possible, it has not been addressed in the literature in the context of the talc/ovarian cancer hypothesis.

**Citation: #8, Cramer et al. Genital talc exposure and risk of ovarian cancer. Int J Cancer 81:351-356, 1999.**

**SUMMARY OF FINDINGS:**

Cramer et al. conducted a population-based case-control study involving 563 ovarian cancer cases. Use of body powders was assessed via personal interview. Use of powder in non-genital areas was not associated with increased ovarian cancer risk (1.08[0.77-1.50]) nor was increased risk seen among those using powder to dust the perineum (1.45[0.97-2.18]), dusting sanitary napkins (1.45[0.68-3.09]) or dusting underwear 1.21 [0.40-3.64]. An elevated risk of ovarian cancer was noted for the exposure categories "multiple uses, genital area", i.e. 2.15(1.30-3.57) and "any personal genital exposure", i.e. 1.6(1.18-2.15).

Dose-response analysis showed an inverse relationship for both frequency of use per month or number of applications of talc. Only one case and three controls reported using cornstarch powders.

The authors conclude that there is a "significant association between the use of talc in genital hygiene and risk of epithelial ovarian cancer."

**ALLEGATIONS OF PETITION'S AUTHORS re: CITATION:**

The authors cite Cramer et al. to document that these investigators suggested institution of "formal public health warnings" in 1999 based on their interpretation of existing data at that time, i.e. that they "confirm" the causal relationship between perineal talc use and ovarian cancer risk.

**MEASURE OF RELATIVE RISK/ODDS RATIO:**

Risk associated with any personal genital exposure to talc, OR=1.60(1.18-2.15)



#### RELEVANCE OF STUDY FINDINGS TO SUPPORT CAUSAL ASSOCIATION:

This population-based case-control study found a statistically significant association between "any personal genital exposure" to talc and risk of ovarian cancer with an odds ratio of 1.60(1.18-2.15). No clear dose-response relationship was seen. In fact, data in both tables II and III suggest an inverse dose-response. Again, as occurs throughout much of the relevant literature, no further explanation for the inconsistent dose-response relationship is offered. The manuscript concedes that, "...it is difficult to quantify the amount of powder actually used..." In essence, they point out the crude nature of the measure of exposure. They acknowledge that a crude exposure measure could also contribute to the finding of a spurious association.

In the discussion of the paper, the authors present a pooled summary odds ratio of fourteen case-control studies in the literature at the time the Cramer et al. report was conducted. The summary OR was 1.36(1.24-1.49). Although the authors point out that this association is statistically significant the p value associated with their assessment of statistical heterogeneity was 0.085. Cramer et al. state that this p value indicates a lack of statistical heterogeneity and therefore suggest that the data show consistency.

The above evaluation of statistical heterogeneity is incorrect in that the threshold p value used in pooled analyses of observational studies, as opposed to randomized clinical trials, is conventionally 0.10 (see Petitti, 2000). The justification for using a much more conservative p value when analyzing epidemiological studies is that they are inherently more variable than randomized trials. Therefore, a p value of 0.085 is consistent with statistical heterogeneity and suggests that the data should not be pooled since the outcome measures across studies vary by a degree greater than would be expected by chance alone. As Huncharek et al. pointed out in their later meta-analysis, clear differences exist between case-control and cohort studies examining the talc/ovarian cancer association. It is essential to seek explanations for these differences (as per Petitti, for instance) rather than ignore the heterogeneity and calculate a pooled estimate of effect. Essentially, Cramer et al. demonstrate that the database they analyzed was not suitable for calculating a pooled odds ratio although they characterize the data as "consistent."

In their Discussion, Cramer et al. also state, "Talc, as a chemical relative of asbestos, appears able to induce histologic changes that are similar to those of asbestos..." As we've pointed out throughout this document and in our recent review article (Muscat, Huncharek, 2008), this is a factual inaccuracy that is repeated in the relevant literature with great frequency. The only similarity between talc and asbestos is that they are both magnesium silicates. Beyond that, the two mineral types share no similar properties. There is a large mineralogical literature detailing the nature of the structure of both asbestos and talc that clearly outlines this fact. The medical literature also contains abundant



information on fiber carcinogenesis. It is largely the morphologic structure of asbestos and other fibers that dictates their toxicity and not their chemical composition. The 3:1 "aspect ratio" of fibers is important in induction of disease and this is independent of chemical composition (see Stanton, 1981). It should be pointed out that many non-fibrous types of asbestos are NOT carcinogenic. Therefore even within the group of asbestos minerals, only a subset of fibrous particles of specific sizes is toxic. A "real-world" example of the composition versus structure issue is the clear difference between diamond and graphite. Both are composed of carbon yet each is distinctly and profoundly different. Diamond is the hardest substance known while graphite is very soft, non-crystalline and brittle. Graphite is also a good conductor of electricity etc. Again, the primary point of importance is that similarity in chemical composition of minerals does not imply similarity in other properties, including biological activity.

**Citation: #9**, Huncharek M et al. Perineal application of cosmetic talc and risk of invasive epithelial ovarian cancer: A meta-analysis of 11,933 subjects from sixteen observational studies. *Anticancer Res* 23:1955-1960, 2003.

#### SUMMARY OF FINDINGS:

This paper presents the results of a meta-analysis designed to evaluate the relationship between perineal dusting with talc and risk of developing ovarian cancer. The rationale for this study was two-fold; (1) Although a possible association between talc use on the female perineum and increased risk of ovarian cancer was first proposed in 1982, the existing literature is inconsistent and the validity of this association is unclear, and (2) meta-analysis provides a systematic, reproducible and transparent method for analyzing large, complex data-sets and appeared well suited to exploring the scientific basis of this proposed association.

Using accepted meta-analytic techniques, data from sixteen observational studies (one cohort and 15 case-control) enrolling 11,933 subjects were statistically pooled. Nine of the sixteen reports showed non-statistically significant odds ratios or relative risks with the one cohort study demonstrating no association between talc use and ovarian cancer. Initial pooling of all 16 reports yielded a summary relative risk of 1.33(1.16-1.45) suggesting a possible positive association, although sensitivity analyses and consideration of causal criteria argued against a causal association.

The assertion by the authors that the use of the summary relative risk statistic of 1.33 is not an appropriate measure to characterize this association is based upon several important findings of the meta-analysis. First, differences in outcome were seen between hospital-based versus population-based case-control studies, i.e. 1.19(0.99-1.41) versus 1.38(1.25-1.41) respectively. This suggests the possible influence of selection bias on study results and/or a "treatment effect" due to short-term talc use by some subjects secondary to treatment induced side effects. Among subjects in population-based studies, there may exist a time



interval between diagnosis and study interview. In this interval some patients may have undergone treatment with modalities such as surgery, radiation and/or chemotherapy. Short-term talc use could be prompted by side effects from treatment such as skin irritation, abdominal bloating etc. The population-based reports may therefore have a larger proportion of prevalent cases versus case-control studies that are more likely to undergo surgery and radiation therapy. Since the majority of women with ovarian cancer present with advanced disease at the time of diagnosis, a larger proportion of subjects in population-based studies may have more limited disease since survival times for advanced ovarian cancer are quite poor (i.e. 5 year survivals under 10%).

Second, demonstration of a dose-response relationship is important for establishment of causal associations. The present data set does not suggest that risk increases with increased exposure and a number of the observational studies show greater disease risk among those in the lowest exposure categories. This may be partially explained by the "treatment effect" phenomenon referred to above. Another possible explanation as discussed in prior portions of this report, is bias secondary to talc use due to disease symptoms. Nonetheless, the lack of a positive dose-response between agent and cause argues against a causal association. The authors conclude, "The available observational data do not support the existence of a causal relationship between perineal talc exposure and an increased risk of epithelial ovarian cancer. Selection bias and uncontrolled confounding may account for the positive associations seen in prior epidemiological studies."

#### ALLEGATIONS OF PETITION'S AUTHORS re: CITATION:

Epstein et al. note, "An analysis of 16 pooled studies **confirmed** (added) a statistically significant 33% increased risk of ovarian cancer associated with the perineal use of talc." Essentially, the petitioners erroneously indicate that the meta-analysis supports an association between perineal talc dusting and ovarian cancer risk, when, in fact, the report clearly states the contrary conclusion, i.e. "The available observational data do not support the existence of a causal relationship between perineal talc exposure and an increased risk of epithelial ovarian cancer."

#### MEASURE OF RELATIVE RISK/ODDS RATIO:

Summary relative risk for association OR=1.33(1.16-1.45) pooling all 16 studies  
Summary relative risk for hospital based studies, OR=1.19(0.99-1.41)  
Summary relative risk for population based studies, OR=1.38(1.25-1.52)

#### RELEVANCE OF STUDY FINDINGS TO SUPPORT CAUSAL ASSOCIATION:

The petition's use of the Huncharek et al. meta-analysis as supporting evidence for a causal association between talc and ovarian cancer is inconsistent with the stated findings of the report, as outlined in both the "Abstract" and "Discussion" sections. As above, the summary relative risk initially obtained by pooling data from all sixteen observational studies (1.33[1.16-1.45]) is of questionable validity



since differences in outcomes were seen across study designs. The one cohort study by Gertig et al. showed negative results while the available case-control differed in outcome depending upon the source of study controls (hospital derived versus population). Studies using hospital derived controls showed no increased risk while those employing population-based controls were consistent with a 38% increased risk of disease.

As discussed in the manuscript, short-term use of talc prompted by symptoms caused by treatment could also bias the population based case-control studies. The proportion of **prevalent** cases enrolled in the study, time from diagnosis and stage of disease at diagnosis, could all contribute to this "treatment effect" and explain the inverse dose-response seen in many studies.

The above discussion clearly points out the fact that the Huncharek et al. meta-analysis of existing data does not support a causal association between talc and ovarian cancer. The authors of the petition mis-interpret the pooled analysis.

**Citation: #10**, Baan R et al. Carcinogenicity of carbon black, titanium dioxide and talc. The Lancet Oncology 7:295-296, 2006.

#### SUMMARY OF FINDINGS:

Citation number 10 is a summary of the recent IARC proceedings during which the carcinogenicity of talc was considered, along with carbon black and titanium dioxide. The summary notes that the one available cohort study (Gertig et al.) failed to show any association between talc use and ovarian cancer risk. Nonetheless, the summary document states that, "Although the cohort study did not lend support to an association, the case-control studies showed a high degree of consistency: the eight **more informative studies** (added) reported a 30-60% increase in risk..." The authors acknowledge that the body of available evidence does not provide evidence of a dose-response relationship.

#### ALLEGATIONS OF PETITION'S AUTHORS re: CITATION:

Epstein et al. cite reference 10 as further support of epidemiological findings of a 30-60% increased risk of ovarian cancer among women using perineal talc and that this report was produced under the auspices of IARC.

#### MEASURE OF RELATIVE RISK/ODDS RATIO:

Citation #10 is a review article and therefore does not present a measure of association derived from a statistical analysis. As above, Baan et al. cite the fact that the IARC deliberations concluded that the "more informative" epidemiological studies suggest a 30-60% increased risk of ovarian cancer among subjects using talc products on the perineum/genitals.

#### RELEVANCE OF STUDY FINDINGS TO SUPPORT CAUSAL ASSOCIATION:



This citation provides a very brief summary of the recent IARC proceedings during which the carcinogenicity of talc was considered. The 2B rating suggests that talc is a possible human carcinogen, at least with regard to ovarian cancer although the IARC summary points out that inhaled talc is not classifiable as a human carcinogen (category 3).

Based on our experience as observers to the relevant IARC proceedings, there are a number of issues that appear to contradict the IARC conclusions. IARC's analysis of the human epidemiological literature is based on the "eight more-informative studies" rather than on the total available epidemiological data. The total epidemiological data do NOT show a "high degree of consistency", as characterized by IARC. For example, the one cohort study on this topic clearly showed no increased cancer risk from talc dusting. The case-control study results differ by design as pointed out by Huncharek et al. (see above) and as seen in the report by Langseth et al. (below). That is, hospital-based studies showed results different from those found via population-based analyses. Neither Epstein nor Baan acknowledge these differences but rather characterize the data as "highly consistent".

Additionally, neither Epstein et al. nor Baan et al. take into consideration the lack of a dose-response relationship in the majority of the epidemiological studies, which would be considered evidence against the suspected association being causal. Huncharek et al., in contrast, addressed this issue and offered possible explanations for this finding based on methodological considerations. All of the above issues suggest the possible influence of bias on the various study results although these issues are not addressed in any substantive way by either set of authors. It is also problematic that neither Baan et al. nor IARC considered the meta-analysis of Huncharek et al. and its findings.

Overall, although the Baan et al. report is held as support for a causal association, the document provides evidence of flaws not only in the pertinent epidemiological evidence itself but also in its erroneous interpretation as causal. It is our opinion that the IARC review of available data on the talc/ovarian cancer association failed to consider the flaws on the relevant database in its entirety. IARC also did not consider the observational data in the context of the criteria recognized as necessary for drawing causal inferences.

**Citation: #11,** Langseth et al. Perineal use of talc and risk of ovarian cancer. J Epidemiol Community Health 62(4):358-360, 2008.

#### SUMMARY OF FINDINGS:

Reference number 11 is a short review article outlining some of the major limitations of the data linking perineal talc use and ovarian cancer. The article also makes some methodological suggestions for future studies in this area.



Langseth et al. cite several aspects of the theory supporting a causal association. These include citing references that suggest talc particles applied to the perineum can migrate to the ovary, that hysterectomy and tubal ligation appear to decrease the risk of ovarian cancer by "removing the pathway by which carcinogenic substances (in this case talc) can reach the ovaries", that the possible mechanism via which talc exerts its carcinogenic effect is inflammation, and finally, that the lack of a demonstrated dose-response may be secondary to the "crudeness of the exposure metric used."

ALLEGATIONS OF PETITION'S AUTHORS re: CITATION:

Epstein et al. cite the Langseth article as supporting the findings of the IARC Monograph 93, i.e. that perineal talc exposure increases ovarian cancer risk 30-60% based upon the eight observational studies cited by IARC.

MEASURE OF RELATIVE RISK/ODDS RATIO:

As in above section.

RELEVANCE OF STUDY FINDINGS TO SUPPORT CAUSAL ASSOCIATION:

As a review, the paper provides no new data to support a causal association. Nonetheless, the authors tend to emphasize aspects of the literature that provide supporting information for the theories put forth by Cramer et al.

Figure 1 in the manuscript is instructive, though, on the difficulty the authors have in substantiating the causal claim. The Figure provides a pooled analysis of available observational studies up to the time of publication of the present review. It's important to note that the pooled OR for population-based studies shows a significant effect (1.40[1.29-1.52]) while pooling the hospital-based analyses gives a null results, i.e. OR of 1.12(0.92-1.36). These results are consistent with the prior meta-analysis published by Huncharek et al. although Langseth et al. largely ignore the above noted problems. Alternative explanations are also plausible that could account for an attenuated effect among hospital-based studies. For instance, hospital derived controls may be more likely to use talc powders over the short-term secondary to their specific hospital admission diagnoses.

The differences in outcome based on study design require explanation and none is offered. In addition, Figure 1 also provides a p value for a test for data heterogeneity, i.e.  $p=0.036$ . A p value of this magnitude indicates the presence of heterogeneity, meaning that the differences in outcome across studies are not due to chance alone. In general, such a finding precludes statistical pooling (see Petitti, 2000) since the studies are not measuring effects of similar magnitudes. The appropriate task in this context is to attempt sensitivity analyses to explain the observed heterogeneity. A pooled odds ratio in the face of heterogeneity is simply not a valid parameter.

Also, in the final portion of the manuscript, Langseth et al. point out, "The current body of experimental and epidemiological evidence is insufficient to establish a causal association between perineal use of talc and ovarian cancer risk." They



also attempt to "explain away" the lack of a dose-response by attributing it, possibly, to the use of a "crude exposure metric", i.e. years of use. Again, this feature of the data cannot be ignored and the crude nature of the exposure measure can, just as readily, account for spurious findings of a positive association in some reports.

Overall, despite the fact that this short review attempts to provide a narrative justification for a talc-ovarian cancer relationship, it serves to point out the many shortcomings of the data base and the numerous sources of flawed reasoning employed in its interpretation.

**Citation: #12**, Merrit MA et al. Talcum powder, chronic pelvic inflammation and NSAIDS in relation to risk of epithelial ovarian cancer. *Int J Cancer* 122:170-176, 2008.

#### SUMMARY OF FINDINGS:

Citation number twelve derives from the Australian Ovarian Cancer Study Group and is a population-based case-control study of 1,576 women with both invasive and borderline ovarian malignancies. The study was designed primarily to address the question as to whether chronic pelvic inflammation is a risk factor for epithelial ovarian cancer.

Although "ever" use of talc was associated with a small increased risk of ovarian cancer, 1.17(1.01-1.36), there was no evidence of increased risk with increased exposure. Regarding inflammatory processes and disease risk, no increased risk of ovarian tumors was associated with pelvic inflammatory disease, endometriosis, human papillomavirus infection, mumps infection or genital herpes, although the latter showed an association with serous tumors, i.e. OR=1.65(1.01-2.69). Neither aspirin nor NSAID use was consistently associated with a decreased risk of ovarian cancer, providing additional evidence against inflammation as a biologically important mechanism in ovarian carcinogenesis.

Another important limitation of this study that should be noted is the relatively low response rates for cases and controls. Only 47% of eligible controls participated, as did only 65% of potential cases.

The authors conclude that, "...on balance, chronic inflammation does not play a major role in the development of ovarian cancer."

#### ALLEGATIONS OF PETITION'S AUTHORS re: CITATION:

The petition cites Merritt et al. as another observational study supporting a positive association between perineal talc use and ovarian cancer risk. Again, this isolated finding is not put in the context of limitations and inconsistencies regarding such issues as dose-response.



MEASURE OF RELATIVE RISK/ODDS RATIO:

For "ever use" talc/ovarian cancer risk: OR=1.17(1.01-1.36)

For talc use at other body sites: OR=1.01(0.84-1.20)

RELEVANCE OF STUDY FINDINGS TO SUPPORT CAUSAL ASSOCIATION:

As seen previously, Epstein et al. isolate the weak positive association shown between "ever" use of talc and ovarian cancer risk from the limitations of the existing data, including the lack of support Merritt et al. provides for the theory underlying talc carcinogenicity, i.e. inflammation. Merritt et al., along with two prior negative meta-analyses on anti-inflammatory medication use in this context, provides cogent evidence against the proposed biological mechanism for the talc/ovarian cancer association. This is even more convincing in that none of the other conditions associated with pelvic inflammation, such as pelvic inflammatory disease (PID) or endometriosis were related to increased risk. Since biological plausibility is a necessary component of causal inference, Epstein et al. ignore a major weakness of their argument and simply concentrate on the odds ratio of 1.17 for "ever" use of perineal talc as the basis for a causal relationship.

**IV. Talc and ovarian cancer risk: A critique of post-1995 data**

**Introduction**

Above, we reviewed literature citations included in the petition to the FDA by Epstein et al. The petition cites some of the relevant literature published since 1995. We also searched electronic databases in order to determine if other citations exist that were not cited either by Epstein et al. or by Huncharek et al. in their 2003 meta-analysis. No additional observational studies relevant to the issue of ovarian cancer causation were located.

The issues articulated by Epstein et al. in relation to the possible carcinogenicity of talc are not uncommon when dealing with interpretation of results derived from observational studies. In an article published twenty years ago, Feinstein provided an insightful and cogent explanation for the myriad problems that plague the process of causal inference as it applies to non-experimental data (Feinstein, 1988). As he points out, most people learn about science by studying experimental methods. These methods largely include direct intervention by the experimenter on whatever entity is under study, whether it be an animal species such as rats or mice, specific chemical compounds, sub-atomic particles etc. The scientist, in this context, directly manipulates the study subject/object using established principles of experimental science. In the context of human studies, the experimental design that has come to represent the "gold standard" of cause-effect relationships is the randomized clinical trial. Unfortunately, in epidemiological research, issues of feasibility and ethical considerations preclude randomization of healthy human subjects to receive potentially harmful exposures to various substances, including those that represent possible carcinogenic hazards. Therefore, the epidemiologist must substitute observational methods to study cause-effect relationships that preclude direct



intervention with, and/or manipulation of, study subjects (i.e. experiments). Because of this fact, criteria for establishing cause-effect relationships are inherently different when utilizing epidemiological methods versus experimental ones.

In 1965, Hill published a landmark article articulating standards for drawing causal inferences from observational data. His rationale for this stemmed from the realization that the urgency of many public health problems demands action despite the fact that existing knowledge might be imperfect (Rothman, 1986). The "Hill Criteria" as they've become known, are not simply a "checklist" of requirements that must be met in order to determine cause-effect relationships. Rather, they represent a theoretical framework to guide one's thinking when attempting to decide whether a body of data meets a basic threshold necessary to distinguish causal from non-causal associations. These criteria include, (1) strength of association, (2) consistency (i.e. repeated observation of an association in different populations under different circumstances), (3) specificity (a given cause leads to a specific effect), (4) temporality (cause must precede effect), (5) biological gradient (dose-response), (6) plausibility (biological plausibility), (7) coherence (i.e. that a given cause/effect relationship for an association does not conflict with what is known of the natural history and biology of the disease in question), (8) experimental evidence (to support the observational findings), (9) analogy.

While the Hill criteria do not provide a complete solution to the dilemma of causal inference in epidemiology, their importance lies in establishing at least a general framework for the process. The proposed talc/ovarian cancer association represents an illustrative example of the utility of this framework. Below we discuss the points raised by Epstein et al. in this context and show that the conclusion that the proposed talc/ovarian cancer association is causal is not supported by existing data.

### **Overview**

The possibility that perineal talc exposure could be associated with development of ovarian cancer was initially derived from a case-control study published in 1982 (Cramer, 1982). Since that time, a number of additional reports have addressed this question with most showing odds ratios ranging between 1.0 and 2.0. Although this has prompted some to suggest that these estimates of effect provide support for a cause-effect relationship between this exposure and disease outcome, several important caveats must be considered.

Effects of this magnitude are often characterized as "weak effects" and although the exact definition of a weak effect is debatable, most epidemiologists would consider associations of less than 2.0 to fall within this general category. Hill and others argue that strong associations are more likely to be causal than weak associations since, "...if they were due to confounding or some other bias, the biasing association would have to be even stronger and would therefore presumably be evident" (Rothman, 1986). As Rothman points out, weak associations are more likely to be explained by undetected biases.



Measures of association of this magnitude are often difficult to interpret. This is based on the fact that the investigator cannot directly manipulate the levels of exposure of interest or extraneous factors that could affect study findings. Attempts to control for external factors are accomplished by statistical manipulations of collected data. However, this process depends on the accuracy and completeness of data collection. Further, the correct choice and interpretation of both statistical models and statistical findings can also be contentious.

It is important to point out that although an association is weak, this does not rule out a causal connection. Nonetheless an example of a factor that could confound the weak effect shown for perineal talc is smoking. It's now recognized that smoking is a risk factor for a number of solid tumors including lung (with OR's on the order of 5.0 versus non-smokers) and esophageal cancer. Evidence exists that smoking may also be related to at least some types of ovarian tumors, in particular, those of the mucinous histology. The current literature contains a number of reports showing a doubling or tripling of mucinous ovarian cancer risk among smokers (Green, 2001)(Pan, 2004). Since Rosenblatt et al. reported that smokers are more likely to engage in perineal talc dusting compared with non-smokers, an imbalance in smokers across case and control groups in epidemiological studies of the talc/ovarian cancer association could contribute to a spurious positive association (Rosenblatt, 1998).

Consistency of an effect could contribute to a causal claim despite a finding of a weak association. Epstein et al. characterize the talc/ovarian cancer relationship as being "confirmed" by multiple scientific publications as well as by review of available evidence by the International Agency for Research on Cancer (IARC). They state that, "...IARC...concluded that eight publications confirmed a 30-60% increased risk of ovarian cancer following the perineal application of talc". Despite the claims of the petitioners, a review of available evidence shows that the epidemiological evidence is NOT consistent across studies or across study types. For instance, Table 1 in Huncharek et al. (2003) shows several inconsistencies in the database. Clearly, not all studies showed a positive, statistically significant association, even among the case-control reports that make up the bulk of the database. In addition, there was relatively wide variation in the magnitude of measures of association.

Interestingly, up to the date of filing of the petition by Epstein et al., only one cohort study had been published, i.e. Gertig et al. (2000) showing no association between perineal talc use and ovarian cancer risk. Given the conflicting findings of case-control studies, Huncharek et al. employed meta-analytic techniques to explore possible sources of variability among these reports. Their rationale for doing so was that if meta-analyses showed that the patterns of low relative risks or odds ratios are consistent across all relevant studies in different populations, these weak associations are less likely to be due to confounding or other biases. If a statistical test for heterogeneity shows effects of different magnitudes across studies, sensitivity analyses can be employed to determine the source of



observed variability and thereby identify biases due to study design, case-control selection etc.

Huncharek et al. initially pooled data from fifteen case-control and one cohort analysis, yielding a summary relative risk (RRs) of 1.33 (1.16-1.45). Although this suggests a statistically significant positive association between perineal talc use and ovarian cancer, risk sensitivity analyses demonstrated clear differences in outcome based on study design. That is, hospital-based case-control studies showed no evidence of an effect (1.19[0.99-1.41]) in contrast to those reports using population-derived controls (1.38[1.25-1.52]). As discussed in the earlier portion of this report, these findings suggest bias and bring the validity of the initial pooled RRs into question. The Huncharek report provides some possible explanation for the observed differences, as was outlined previously, and indicates that study outcomes are not consistent.

Further supporting the findings of this meta-analysis is the more recent and updated pooled data provided by Langseth et al. (2008) cited by the Epstein petition. These authors pooled data from twenty relevant epidemiological studies. Again, although the calculated summary relative risk obtained from pooling data from all 20 reports gives a statistically significant RRs (pooled odds ratio) of 1.35(1.26-1.46), the statistical test for data heterogeneity yielded a p value of 0.036. A p value of this size (i.e. less than 0.10) is indicative of significant heterogeneity and, as per convention (see Petitti) precludes statistical pooling, i.e. the pooled summary estimate of effect is not valid given that the data are heterogeneous. This shows that the available data are not consistent and therefore makes a causal association less likely.

One of the more persistent findings among the epidemiological studies examining this suspected association is the lack of a dose-response relationship. Table 2 of the Huncharek et al. meta-analysis displays dose-response data for those included studies providing such information. Many of the reports do not show increased risk with increasing exposure. The even more problematic finding in terms of establishing a causal association is that a number of studies suggest that risk decreases with increased exposure, (e.g. see Chang and Risch above or Cook et al., 1997).

Few authors directly address the above noted lack of evidence of a dose – response. Huncharek et al. (2003, Petition reference #9) and Huncharek and Muscat (2007), in contrast, offer a number of possible explanations for an inverse dose response. As outlined above, treatment for ovarian cancer may induce specific symptoms that could prompt short-term talc use. For instance, some early stage patients may undergo radiation therapy, which causes skin irritation. Such side effects could result in some patients using talc products to address these side effects. Talc is often recommended to keep skin folds in the perineum dry and prevent skin breakdown secondary to radiation. In addition, symptoms of the disease process itself could cause some women to use talc to counter these symptoms. Paulsen et al. (2005) and Golf et al. (2004) document that a number of symptoms are quite common among ovarian cancer cases versus



control patients. For instance, Golf et al. (2004) show that increased abdominal size is over seven times more common among cases versus controls while abdominal bloating is 2.5 times more common. The combination of bloating, increased abdominal size and urinary symptoms were found in almost half of all ovarian cancer patients but in only 8% of controls. Also of interest are the findings of Green et al. (1997, Petition reference #8) that increased ovarian cancer risk was seen among patients with painful periods or excessive vaginal bleeding. Again, such symptoms could prompt talc use and lead to a spurious association with talc. Although there are no firm data in the existing literature to definitively establish that these factors lead to increased short-term use of talc, the scenarios are plausible and could explain the inverse dose-response seen in a number of epidemiological studies.

The majority of reports largely ignore the counter-intuitive findings although Cramer et al. (Petition reference #4) attribute the dose-response inconsistencies, possibly, to the "crudeness" of the exposure measurement used. What is not acknowledged is that this same problem of imprecise exposure estimates could also explain a spurious positive association of talc and ovarian cancer, especially in light of the inconsistent outcomes across reports. In summary, the failure to show a coherent and consistent relationship between talc exposure and ovarian cancer risk argues against a causal association.

An additional limitation of the existing literature dealing with the proposed talc/ovarian cancer association is the lack of any known biological mechanism via which talc particles could induce ovarian tumors. This represents probably the most troublesome aspect of arguments in support of this proposed causal association. It is also interesting to note, that biologically theories put forth to explain how talc may cause neoplastic transformation have changed over time as various proposed mechanisms have met with criticism in the developing literature.

Initially, Cramer et al. (1982) and others sought to draw an analogy between talc and fibrous asbestos, the latter being a known and well-described carcinogen. The biological effects of asbestos have been elucidated over the last 50-60 years via a multitude of epidemiological, in vitro and in vivo studies (Huncharek, 1986). Specific asbestos types are recognized as both animal and human carcinogens and, due to this fact, this commodity is banned from use in the United States. A number of investigators initially implicated talc products as possible carcinogens since prior to the early 1970's, some talc products contained small amounts of asbestos fibers (Rohl, 1976). Clearly, such products could possibly represent a carcinogenic risk secondary to the asbestos contamination. It should be pointed out that this in no way implicates talc as a toxin since the problematic constituent of such products was the asbestos fibers, not talc.

Since the early 1970's, the relevant industries voluntarily eliminated asbestos contamination from talc products. Because of this, the "anti-talc" argument shifted to implicate talc itself as a carcinogenic risk based on its "chemical similarity" to talc. It is interesting, and confusing, as to why talc is thought by



some to be carcinogenic based on the fact that there is some common chemical constituents of talc and asbestos.

Both commercial talc and the group of minerals known as asbestos are magnesium silicates. Beyond that fact, the two substances share no common characteristics. The work of Stanton (1981, referenced below) and others shows that the carcinogenic ability of fibrous asbestos is due to its structure, not its chemical composition. While talc and asbestos are both magnesium silicates, they are structurally distinct and belong to different mineral groups and subgroups, as detailed by Muscat and Huncharek (2008). Amphibole asbestos minerals are inosilicates while talc is a member of the silicate subclass phyllosilicate and group clay or montmorillonite/smectite. While serpentines, including serpentine asbestos (chrysotile), are also phyllosilicates, serpentine minerals belong to the kalolinite-serpentine group. The asbestos varieties of serpentine are structurally different from other members of the serpentines in that their brucite layers and silicate layers bend into tubes that produce fibers. Non-fibrous serpentine does not have carcinogenic properties and it is clear that the physical structure of serpentine asbestos (and amphibole asbestos) is responsible for its disease-causing potential, not its atomic constituents. It simply does not follow that one should assume talc is carcinogenic simply because it is a silicate. Structure dictates toxicity/carcinogenicity, not chemical composition.

Earlier in this report, we use the analogy of graphite and diamond as an example of two substances that are chemically identical yet are vastly different in their physical properties. The contrast between commercial talc and any of the varieties of fibrous asbestos is just as stark. Clearly, the "asbestos analogy" used to support the possible carcinogenicity of talc is not supported by existing data.

Given the dissimilarities between talc and asbestos with regard to their fibrous shapes, the weak but increased associations in the epidemiological studies could be attributed to other mechanisms, assuming that the statistical associations are unbiased and not due to confounding. Asbestos fibers in the lung initiate an inflammatory and scarring process, and it has been proposed that ground talc, as a foreign body, might initiate an inflammatory response (Ness, 1999). Pelvic inflammatory diseases, however, such as endometriosis, peritonitis, tubo-ovarian abscess formation etc., have not been associated with an increased risk of ovarian cancer. A meta-analysis of studies of anti-inflammatory drug use found no reduction in ovarian cancer risk (see Muscat, Huncharek, 2008). In fact, the Merritt et al. study (2007) cited by Epstein et al. also showed no relationship between inflammation and ovarian cancer risk.

Most recently, Cramer et al. proposed that the talc/ovarian cancer association might be explained by the induction of Anti-MUC1 antibodies (Cramer, 2005). This idea has been debated on statistical grounds where talcum powder applied to the perineum was associated with increased Anti-MUC1 expression but the correlation was also observed when talc powder was applied to other body parts. More importantly, the simple observation that talc elevates immunoglobulin protein levels in blood, possibly via heat shock proteins, seems to



have no known direct relevance for ovarian cancer since Anti-MUC1 is associated with other cancers and because there is no known role of heat shock proteins in ovarian cancer risk.

Some of the most important biological data supporting the non-toxic nature of talc comes from the clinical use of talc in treating both malignant and benign pleural effusions in humans (i.e. pleurodesis). This is a common procedure in the United States and elsewhere and talc slurry is applied directly to the pleura (via chest tube placement) to induce obliteration of the pleural space by scarring and prevent the re-accumulation of fluid secondary to tumor or benign causes. Multiple long-term clinical studies, as reviewed by Muscat and Huncharek (2008), have not shown a single case of cancer secondary to direct talc application to the human pleura. In an earlier part of this report, we also detailed recent data showing that talc has demonstrated anti-tumor properties secondary to the induction of endostatin when used in pleurodesis. In fact, pleurodesis patients treated with talc are known to experience longer survival times than those treated with other sclerosing agents. This is likely due to the tumor-inhibitory effects of talc, as suggested by a number of investigators.

Finally, other human data, such as the demonstration that inhaled talc in mining and milling operations is not associated with increased pulmonary tumors and the likelihood that talc could selectively induce ovarian cancer and not lung cancer at exposure concentrations orders of magnitude lower than that experienced in occupational settings argues against its toxicity.

Although the process of drawing causal inferences from scientific data is complex, application of accepted standards, as noted above, to the talc/ovarian cancer relationship clearly indicates that the available epidemiological and other evidence does not support a causal connection. The weak association shown in a sub-set of observational studies can potentially be explained by numerous alternative hypotheses, as detailed throughout this document. Given the lack of supporting evidence from in vivo, in vitro and clinical research studies using human subjects, the weak epidemiological association is unlikely to be causal.

#### **V. Review of Cancer Prevention Coalition website**

There are a number of factual errors on the CPC website. The page containing answers to specific questions begins with a description of talc. The first sentence implies that talc contains "fibers" that are "similar" to asbestos, that are not "separated" from mined talc. This implies to the lay reader that all talc preparations contain particles of "asbestos like" fibers. This could be misunderstood by the public as implying that all talc contains potentially cancer-causing particles, contrary to established fact.

Under the section explaining "Why is talc harmful", it is stated that talc has been shown to cause tumors of the ovary. It is also stated that talc shares dangerous similarities to the "potent carcinogen", asbestos, without further elaboration. In



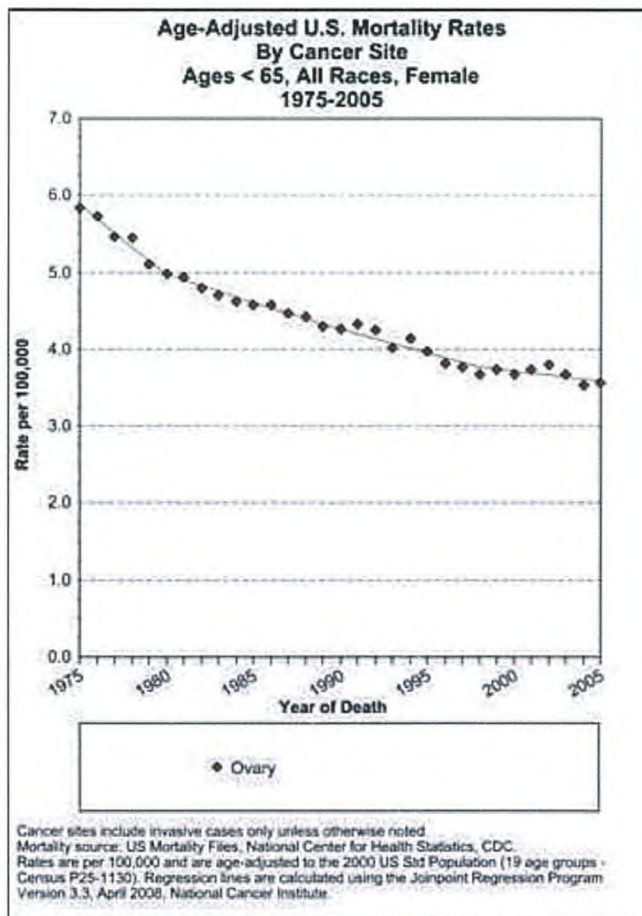
their discussion of what type of talc exposures are dangerous, the site plainly states that talc is a carcinogen and that there exists a strong link between frequent use of talc in the genital area and ovarian cancer. They also go on to state that talc should not be used on children since it is carcinogenic.

In the last paragraph of the "Risks of Talcum Powder" page, they urge consumers not to purchase talc products and to write to the FDA to express concerns regarding talc's toxicity.

Clearly, the CPC website contains multiple errors of fact and mis-representations. All of these are addressed in the earlier portions of this report.

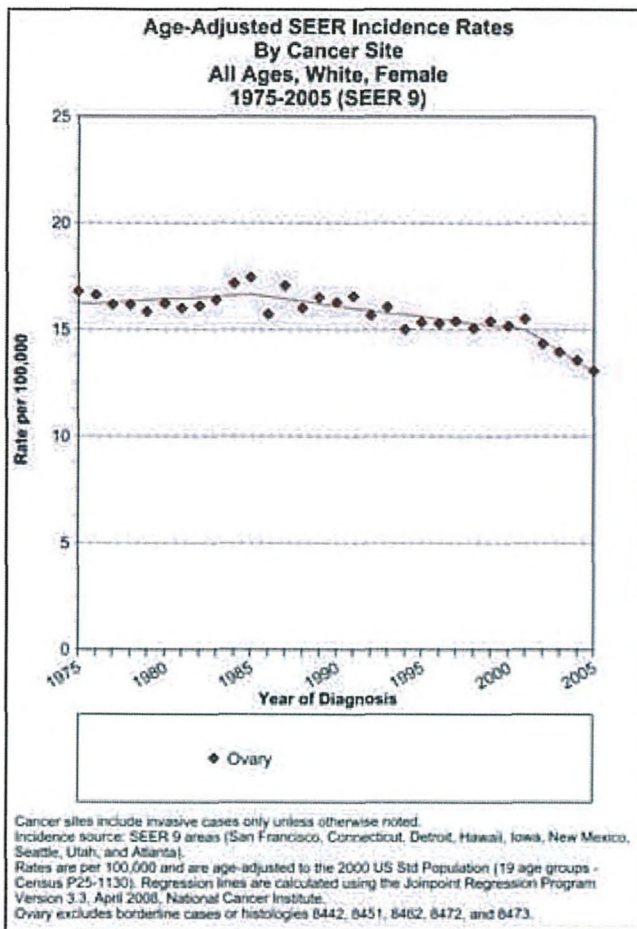
## VI. Appendix

Relevant SEER data

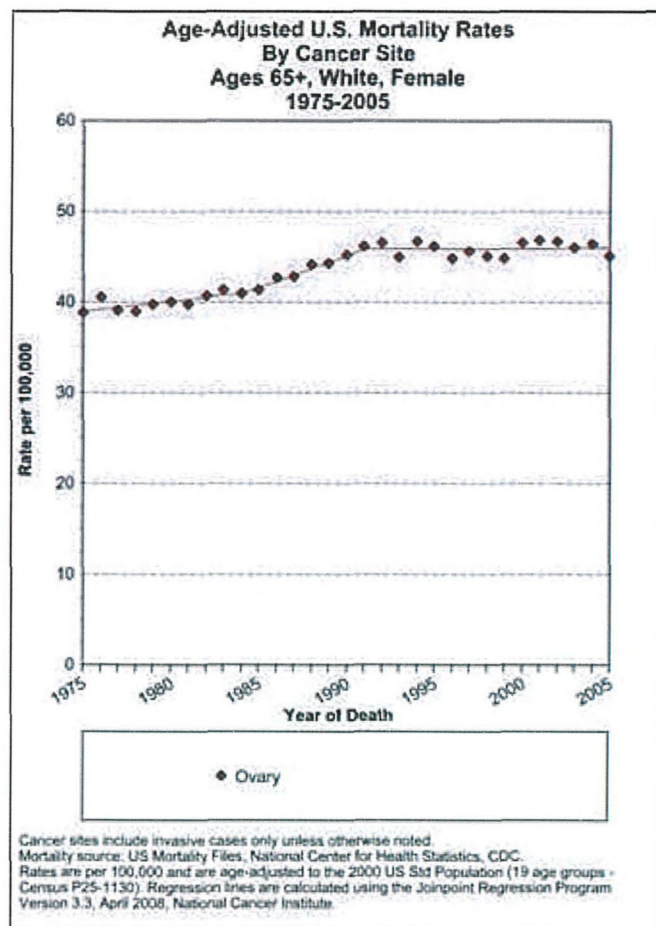




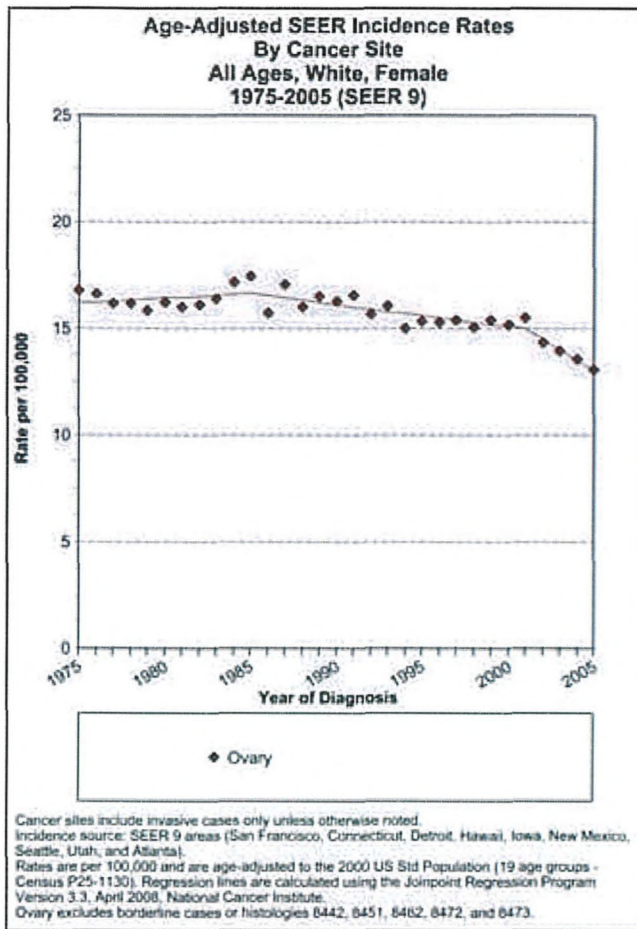
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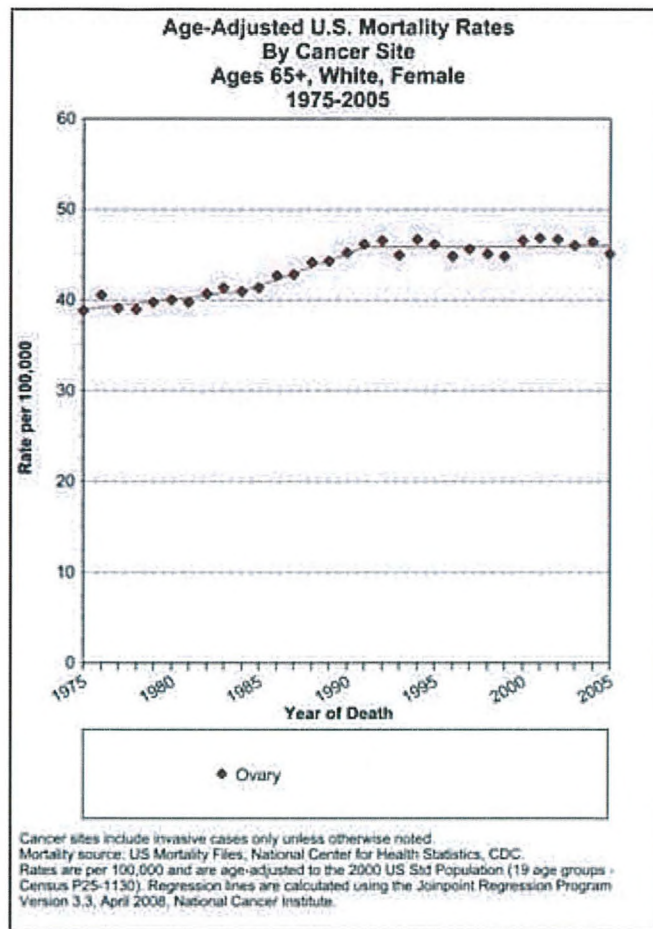




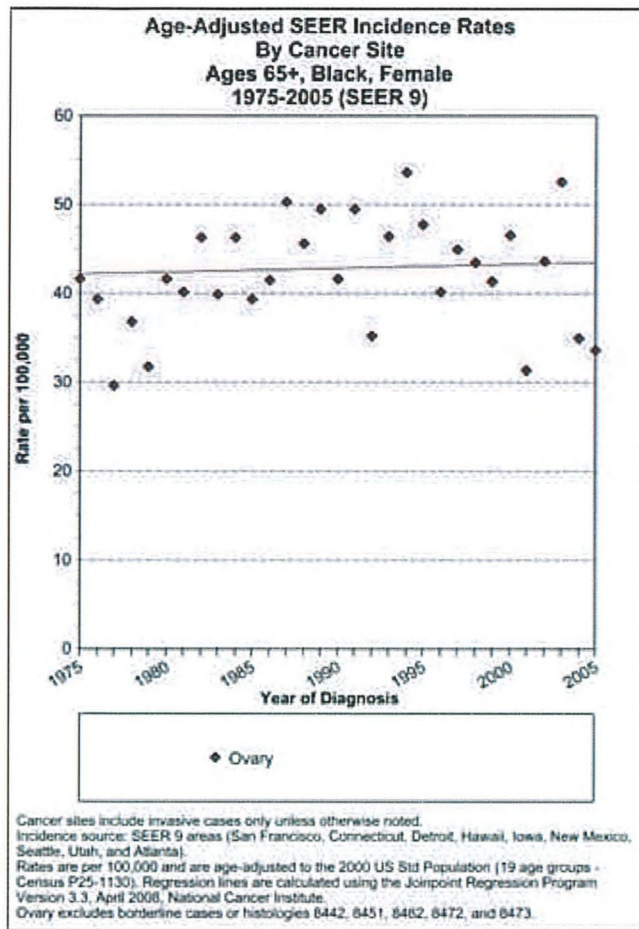




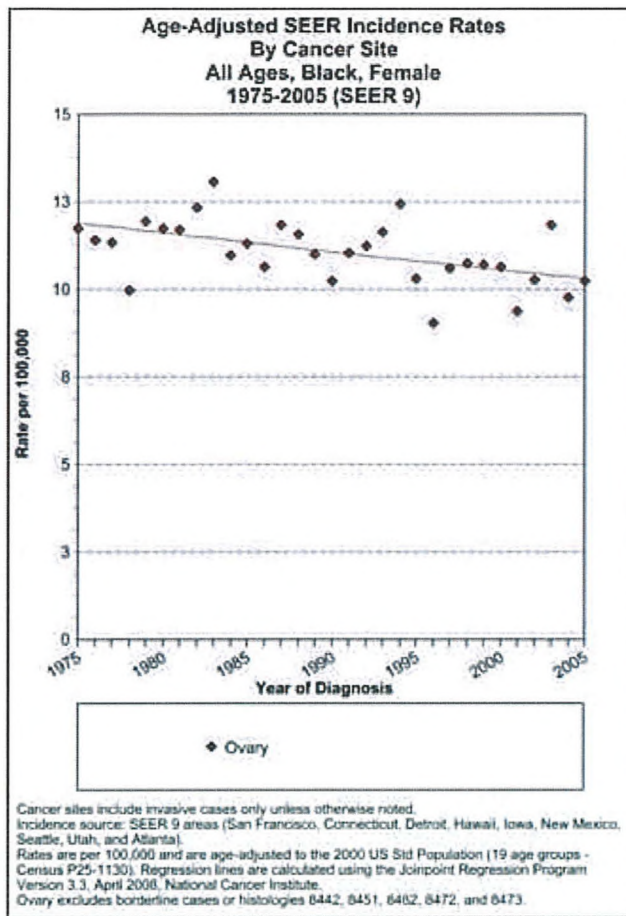














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# Exhibit 157



Joshua E. Muscat, Ph.D.

Page 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NEW JERSEY

- - -

IN RE: JOHNSON & :  
JOHNSON TALCUM POWDER :  
PRODUCTS MARKETING, :  
SALES PRACTICES, AND : NO. 16-2738  
PRODUCTS LIABILITY : (FLW) (LHG)  
LITIGATION :  
:  
THIS DOCUMENT RELATES :  
TO ALL CASES :

- - -

September 25, 2018

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Videotaped deposition of  
JOSHUA E. MUSCAT, Ph.D., taken pursuant  
to notice, was held at the law offices of  
Drinker Biddle & Reath, One Logan Square,  
Philadelphia, Pennsylvania, beginning at  
9:45 a.m., on the above date, before  
Michelle L. Gray, a Registered  
Professional Reporter, Certified  
Shorthand Reporter, Certified Realtime  
Reporter, and Notary Public.

- - -

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Joshua E. Muscat, Ph.D.

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<p style="text-align: right;">Page 14</p> <p>1           - - -</p> <p>2           THE VIDEOGRAPHER: We are</p> <p>3           now on the record. My name is</p> <p>4           David Lane, videographer for</p> <p>5           Golkow Litigation Services.</p> <p>6           Today's date is September 25,</p> <p>7           2018. Our time is 9:45 a.m.</p> <p>8           This deposition is taking</p> <p>9           place in Philadelphia,</p> <p>10          Pennsylvania, in the matter of</p> <p>11          Talcum Powder Litigation MDL.</p> <p>12          Our deponent today is</p> <p>13          Dr. Joshua Muscat.</p> <p>14          All counsel will be noted on</p> <p>15          the stenographic record.</p> <p>16          The court reporter is</p> <p>17          Michelle Gray who will now swear</p> <p>18          in our witness.</p> <p>19          - - -</p> <p>20          ... JOSHUA E. MUSCAT, Ph.D.,</p> <p>21          having been first duly sworn, was</p> <p>22          examined and testified as follows:</p> <p>23          - - -</p> <p>24          EXAMINATION</p>	<p style="text-align: right;">Page 16</p> <p>1           Q. You are not a geologist?</p> <p>2           A. No.</p> <p>3           Q. You are not a gynecologist?</p> <p>4           A. That's correct.</p> <p>5           Q. Okay. Briefly, would you</p> <p>6           tell us, and I mean briefly because we've</p> <p>7           got a lot of ground to cover. What is an</p> <p>8           epidemiologist and what does an</p> <p>9           epidemiologist do?</p> <p>10          A. Okay. Actually comes from</p> <p>11          the word, the word epidemos. It's</p> <p>12          actually a Greek word. It means upon</p> <p>13          people. So what it really means, it's</p> <p>14          the study of the distribution causes of</p> <p>15          diseases within populations.</p> <p>16          Q. Okay. And just to kind of</p> <p>17          put it in words a jury and judge might</p> <p>18          understand, epidemiology just describes</p> <p>19          cause and effect relationships of</p> <p>20          diseases in human beings?</p> <p>21          MR. SILVER: Object to form.</p> <p>22          MR. HEGARTY: Object to</p> <p>23          form.</p> <p>24          THE WITNESS: It can</p>
<p style="text-align: right;">Page 15</p> <p>1           - - -</p> <p>2           BY MR. TISI:</p> <p>3           Q. Good morning.</p> <p>4           A. Good morning.</p> <p>5           Q. Would you state your name,</p> <p>6           please?</p> <p>7           A. Joshua Muscat.</p> <p>8           Q. And where is your</p> <p>9           professional address?</p> <p>10          A. 500 University Boulevard,</p> <p>11          Hershey, Pennsylvania.</p> <p>12          Q. So you live in Pennsylvania?</p> <p>13          A. That's correct.</p> <p>14          Q. Now, you were introduced as</p> <p>15          a doctor. Are you a medical doctor?</p> <p>16          A. No.</p> <p>17          Q. You are what's called an</p> <p>18          epidemiologist, is that right?</p> <p>19          A. That's correct.</p> <p>20          Q. And you are not a</p> <p>21          toxicologist, are you?</p> <p>22          A. No.</p> <p>23          Q. You are not a mineralogist?</p> <p>24          A. No.</p>	<p style="text-align: right;">Page 17</p> <p>1           ultimately be used for those</p> <p>2           purposes. But the main purpose is</p> <p>3           to test statistical associations.</p> <p>4           BY MR. TISI:</p> <p>5           Q. Okay. Now, would you agree</p> <p>6           that while epidemiology is a science, the</p> <p>7           decision as to whether or not the weight</p> <p>8           of the evidence supports a causal</p> <p>9           inference is one upon which reasonable</p> <p>10          epidemiologists can disagree?</p> <p>11          MR. HEGARTY: Objection to</p> <p>12          form.</p> <p>13          MR. HUDSON: Object to form.</p> <p>14          THE WITNESS: I'm sorry, can</p> <p>15          you repeat that, please?</p> <p>16          BY MR. TISI:</p> <p>17          Q. Yes. Would you agree that</p> <p>18          while epidemiology is a science, the</p> <p>19          decision as to whether the weight of</p> <p>20          evidence supports a causal inference is</p> <p>21          one upon which reasonable epidemiologists</p> <p>22          may disagree?</p> <p>23          MR. HUDSON: Objection to</p> <p>24          form.</p>

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<p>1 THE WITNESS: It really 2 depends on the topic. You know, I 3 think that no one would disagree 4 for example, that smoking caused 5 lung cancer. If someone disagreed 6 with that, I would say they are 7 unreasonable. 8 BY MR. TISI: 9 Q. But there were times in the 10 past when the science was evolving that 11 epidemiologists lined up on both sides of 12 that particular question, correct? 13 MR. HEGARTY: Objection to 14 form. 15 THE WITNESS: I can't recall 16 the history of it. I would say 17 that at least the ones that I'm 18 familiar with certainly did not 19 line up on both sides. 20 MR. SILVER: Just so we 21 don't have to all say: An 22 objection for one is an objection 23 for all? 24 MR. TISI: That's correct.</p>	<p>1 Q. And -- and they would -- 2 there were epidemiologists who strongly 3 disagreed with him, correct? 4 A. I don't know whether they 5 were epidemiologists or not. 6 Q. But there were people that 7 strongly disagreed with him? 8 MR. HEGARTY: Objection to 9 form. 10 THE WITNESS: On a priori, 11 yes. 12 BY MR. TISI: 13 Q. Now, I'm going to show you a 14 copy of your curriculum vitae which has 15 been produced to us in this case. I'm 16 going to mark that as Exhibit Number 1. 17 (Document marked for 18 identification as Exhibit 19 Muscat-1.) 20 BY MR. TISI: 21 Q. Now, Doctor, we previously 22 served you with a subpoena for -- you 23 know we're here for the talc litigation, 24 correct?</p>
Page 19	Page 21
<p>1 BY MR. TISI: 2 Q. Well, you raised the 3 question. You know over the past 4 50 years there were epidemiologists on 5 one side of the cigarette debate that 6 thought that there was inadequate 7 evidence to support the conclusion that 8 cigarette smoking caused lung cancer. 9 And then there were epidemiologists who 10 came to that decision a lot earlier, 11 correct? 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: I don't have 15 any recollection of specific 16 epidemiologists that objected to 17 that. 18 My mentor was actually the 19 one who found, way back when in 20 1950, who found the association 21 between smoking and lung cancer. 22 BY MR. TISI: 23 Q. That was Dr. Wynder? 24 A. Pronounced Wynder, right.</p>	<p>1 A. That's correct. 2 Q. And you know that the 3 plaintiffs in this case previously served 4 you with a subpoena asking you for 5 documents related to your involvement 6 with that issue, correct? 7 A. That's correct. 8 Q. And I'm going to show you a 9 copy of the subpoena that we served in 10 this case. 11 (Document marked for 12 identification as Exhibit 13 Muscat-2.) 14 BY MR. TISI: 15 Q. I'd like to mark that as 16 Exhibit Number 2. 17 Have you seen that before, 18 sir? 19 A. No, I don't recall seeing 20 this. 21 Q. Okay. All right. Did you 22 collect documents in connection with a 23 subpoena that you were provided in this 24 case?</p>

6 (Pages 18 to 21)



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Page 22	Page 24
<p>1 A. Yes, I did. 2 Q. And did you provide them to 3 your counsel? 4 A. Yes, I did. 5 Q. Did you provide them -- do 6 you know if your counsel provided them to 7 the defendants in this case, Johnson &amp; 8 Johnson, before they were produced to us 9 for review? 10 A. My understanding is -- not 11 entirely sure what documents were 12 produced. 13 Q. Okay. Do you understand 14 that your documents were produced to 15 Johnson &amp; Johnson before they were 16 produced to us? 17 A. I'm not sure. 18 Q. Okay. I'd like to attach -- 19 in connection with your subpoena, the 20 defendants in this case, or your counsel, 21 excuse me, produced what's called a 22 privileged log. Do you know what that 23 is? 24 A. I've heard the term.</p>	<p>1 on the grounds of alleged privilege. Do 2 you see that? 3 A. Yeah. I'm not entirely sure 4 how to read this, but -- 5 Q. Yeah, I understand. But you 6 understand that a considerable number of 7 documents were withheld from our review 8 because of your relationship with the 9 defendants in this case? 10 MR. SILVER: Objection to 11 form. 12 THE WITNESS: So I 13 understand that certain documents 14 were privileged, okay. 15 BY MR. TISI: 16 Q. Right. And they are 17 privileged because you had a relationship 18 with the defendants in this case, Johnson 19 &amp; Johnson, Imerys, PCPC and any 20 combination of those people, correct? 21 MR. HUDSON: And, 22 Dr. Muscat, I'm going to instruct 23 you not to answer if the answer 24 would be information that you</p>
Page 23	Page 25
<p>1 Q. And do you know -- I'm going 2 to attach it as Exhibit Number 3. 3 (Document marked for 4 identification as Exhibit 5 Muscat-3.) 6 BY MR. TISI: 7 Q. A privilege log are 8 documents that were withheld by your 9 lawyer in this case -- 10 A. Okay. 11 Q. -- from production to us, 12 the plaintiffs, on the grounds that there 13 was some reason to believe that your 14 relationship with them and the documents 15 that you produced in the context of that 16 relationship, we don't get to see those. 17 Do you understand that? 18 MR. HUDSON: Objection. 19 THE WITNESS: I understand, 20 yes. 21 BY MR. TISI: 22 Q. Okay. And Exhibit Number 3 23 is the list of documents that were 24 withheld from the plaintiffs in this case</p>	<p>1 learned in discussions with 2 counsel in this case. If you 3 otherwise know the answer, you're 4 free to respond. 5 THE WITNESS: Okay. 6 MR. LOCKE: I want to note 7 an objection to form. 8 THE WITNESS: Can you repeat 9 the question, please? 10 BY MR. TISI: 11 Q. Let me rephrase the 12 question. 13 A. Yeah. 14 Q. You know that there are a 15 considerable number of documents here -- 16 A. Right. 17 Q. -- that were withheld from 18 us -- withheld from our view, correct? 19 A. Right. 20 Q. And you know that those 21 documents were withheld because you have 22 a -- you have and have had a relationship 23 with every one of the defendants in this 24 talc litigation, correct?</p>

7 (Pages 22 to 25)



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<p style="text-align: right;">Page 26</p> <p>1 MR. HUDSON: Objection to 2 form. 3 And same instruction, 4 Dr. Muscat, if the answer is 5 derived from information that was 6 learned from your discussions with 7 counsel, I instruct you not to 8 answer. If you know the answer, 9 you are otherwise free to respond. 10 THE WITNESS: Okay. So I 11 guess I choose not to answer. 12 BY MR. TISI: 13 Q. Okay. So you don't want -- 14 okay. 15 You do -- you have had a 16 relationship over the past decade with 17 every defendant in this litigation, 18 correct? 19 MR. HUDSON: Objection to 20 form. 21 THE WITNESS: So I'm not 22 sure what you mean by 23 relationship. In terms of the 24 withholding of any documents to</p>	<p style="text-align: right;">Page 28</p> <p>1 Imerys over the course of the past 2 20 years, correct? 3 MR. SILVER: Objection to 4 form. 5 BY MR. TISI: 6 Q. Previously Rio Tinto or 7 Luzenac? 8 MR. HUDSON: Objection to 9 form. 10 THE WITNESS: Have I worked 11 with them? No, not directly. 12 BY MR. TISI: 13 Q. But you work with them 14 indirectly because you work with their 15 lawyers, correct? 16 A. That's correct. 17 Q. You worked with their 18 lawyers Crowell &amp; Moring, correct? 19 A. I had a meeting with them, 20 that's correct. 21 Q. You had more than one 22 meeting, correct? 23 A. One meeting. 24 Q. You also met with -- you</p>
<p style="text-align: right;">Page 27</p> <p>1 any of those parties, whether I 2 had a relationship or however you 3 want to define it, I wasn't part 4 of that process. 5 BY MR. TISI: 6 Q. I'm not asking you that 7 question, sir, I moved on. 8 A. Yeah. Okay. 9 Q. My question is, you have had 10 a relationship with Johnson &amp; Johnson, 11 correct, over the years? 12 MR. HUDSON: Objection to 13 form. 14 THE WITNESS: I've had a 15 consulting relationship. 16 BY MR. TISI: 17 Q. You've actually been an 18 expert for them as well, correct? 19 A. That's correct. 20 Q. All right. You have worked 21 with their lawyers Shook Hardy &amp; Bacon, 22 correct? 23 A. That's correct. 24 Q. And you have worked with</p>	<p style="text-align: right;">Page 29</p> <p>1 know who Bob Glenn is? 2 A. Yes. 3 Q. Who is Bob Glenn? 4 A. He is a toxicologist. 5 Q. He is more than a 6 toxicologist. He was a consultant for 7 the lawyers for Imerys, correct? 8 MR. HUDSON: Objection to 9 form. 10 THE WITNESS: That I don't 11 know. 12 BY MR. TISI: 13 Q. You know that he was working 14 with Crowell &amp; Moring, do you not, the 15 law firm of Crowell &amp; Moring? 16 A. Yes. 17 Q. Okay. And you also worked 18 with the PCPC, the Personal Care Products 19 Council? 20 MR. HUDSON: Objection to 21 form. 22 THE WITNESS: Me? 23 BY MR. TISI: 24 Q. Yes.</p>

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<p style="text-align: right;">Page 30</p> <p>1 A. No.</p> <p>2 Q. You never worked with them,</p> <p>3 you never prepared reports for them?</p> <p>4 A. That's correct.</p> <p>5 Q. Okay. Did you prepare</p> <p>6 reports for any of their consultants?</p> <p>7 Do you know who The Weinberg</p> <p>8 Group is?</p> <p>9 MR. HUDSON: Objection to</p> <p>10 form.</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Okay. Do you know The</p> <p>14 Weinberg Group worked for PCPC?</p> <p>15 MR. LOCKE: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: The Weinberg</p> <p>18 Group worked for PCPC.</p> <p>19 BY MR. TISI:</p> <p>20 Q. And they were a consultant</p> <p>21 group, correct?</p> <p>22 A. Weinberg Group is a</p> <p>23 consulting group, that's correct.</p> <p>24 Q. And you worked with them to</p>	<p style="text-align: right;">Page 32</p> <p>1 Q. Okay. Well, let me help</p> <p>2 you.</p> <p>3 A. Okay.</p> <p>4 Q. Let me help you. Johnson &amp;</p> <p>5 Johnson, you've had a relationship with</p> <p>6 them?</p> <p>7 A. Yes, that's correct.</p> <p>8 Q. And your relationship with</p> <p>9 them on the talc-related issues goes back</p> <p>10 to the 1990s when you met -- when you met</p> <p>11 under a contract with American Health</p> <p>12 Foundation, correct?</p> <p>13 MR. HEGARTY: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: I did meet</p> <p>16 with them, that's correct.</p> <p>17 BY MR. TISI:</p> <p>18 Q. All right. And you worked</p> <p>19 in consultation with Imerys, directly or</p> <p>20 indirectly, through their lawyers in the</p> <p>21 2000s which was Crowell &amp; Moring,</p> <p>22 correct?</p> <p>23 A. That's correct.</p> <p>24 Q. And you worked with the</p>
<p style="text-align: right;">Page 31</p> <p>1 prepare reports for groups who were</p> <p>2 involved in the regulation of talc,</p> <p>3 correct?</p> <p>4 MR. HEGARTY: Objection to</p> <p>5 form.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Like the -- let me rephrase.</p> <p>8 A. So --</p> <p>9 Q. Go ahead.</p> <p>10 A. So yes, I did work for The</p> <p>11 Weinberg Group on behalf of 2000 NTP</p> <p>12 submission.</p> <p>13 Q. And we're going to go over</p> <p>14 some of those things. But I'm going to</p> <p>15 go back to my question here.</p> <p>16 You have had a relationship</p> <p>17 either directly or indirectly with every</p> <p>18 defendant who is sitting around this</p> <p>19 table, correct?</p> <p>20 MR. HUDSON: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: Well, I don't</p> <p>23 know who is here.</p> <p>24 BY MR. TISI:</p>	<p style="text-align: right;">Page 33</p> <p>1 personal -- the PCPC, the trade</p> <p>2 organization for talc, from the 2000 time</p> <p>3 frame related to talc issues and ovarian</p> <p>4 cancer through The Weinberg Group?</p> <p>5 MR. HEGARTY: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: So I think at</p> <p>8 that time that was the CTFA, is</p> <p>9 that correct?</p> <p>10 BY MR. TISI:</p> <p>11 Q. Correct.</p> <p>12 A. Okay. So I never worked</p> <p>13 with them.</p> <p>14 Q. Right, but you worked</p> <p>15 indirectly with them through their --</p> <p>16 through their consultants which was The</p> <p>17 Weinberg Group, correct?</p> <p>18 MR. HUDSON: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: So I worked</p> <p>21 with The Weinberg Group, that's</p> <p>22 correct.</p> <p>23 BY MR. TISI:</p> <p>24 Q. And you know The Weinberg</p>



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<p style="text-align: right;">Page 34</p> <p>1 Group submitted your report to the 2 national toxicology program relating to 3 talc, correct? 4 MR. HUDSON: Objection to 5 form. 6 THE WITNESS: They submitted 7 my report to the NTP, that's 8 correct. 9 BY MR. TISI: 10 Q. Correct. Under the name 11 CTFA. 12 A. So I think the CTFA as I 13 recall, they are the ones who submitted 14 my report to the NTP. 15 Q. Correct. And they are the 16 trade organization for the defendants who 17 are sitting around this table, Johnson &amp; 18 Johnson and the mining company, who at 19 that time was Luzenac, correct? 20 MR. HEGARTY: Objection. 21 Objection to form. 22 THE WITNESS: So I don't 23 have any knowledge of that. 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 36</p> <p>1 epidemiology relating to the question of 2 whether or not talcum powder products 3 cause ovarian cancer? 4 MR. HUDSON: And Dr. Muscat, 5 I'll instruct you not to answer if 6 your answer is derived from 7 discussions you've had with 8 counsel in this case. 9 If you otherwise know the 10 answer to the question, you are 11 free to respond. 12 THE WITNESS: Okay. I don't 13 know the questions that are 14 being -- so I didn't come here 15 with a prior knowledge that I was 16 going to answer those questions. 17 But I understand now. 18 BY MR. TISI: 19 Q. Okay. Do you know -- I'm 20 going to ask you about public statements 21 that you made and things that you wrote 22 in the literature relating to ovarian 23 cancer and talc. 24 A. Okay.</p>
<p style="text-align: right;">Page 35</p> <p>1 Q. You have no knowledge of 2 that, Doctor? 3 A. No. 4 Q. Okay. We'll get into that 5 in a little bit. 6 A. Okay. 7 Q. Now, let's get to the point 8 of why we're here today. 9 You understand that we're 10 here to discuss your involvement in the 11 evolution, conduct, and interpretation of 12 epidemiology relating to the question of 13 whether or not talcum powder products 14 caused or contributed to the development 15 of ovarian cancer? 16 MR. HEGARTY: Objection to 17 form. 18 THE WITNESS: I'm sorry, can 19 you repeat that? 20 BY MR. TISI: 21 Q. Yes. Do you understand that 22 we are here to ask you questions about 23 your involvement in the evolution, 24 conduct, and interpretation of the</p>	<p style="text-align: right;">Page 37</p> <p>1 Q. Okay. And, in fact, over 2 the past 20 years or so, even more, you 3 have actually written on this topic, 4 correct? 5 A. That's correct. 6 Q. Okay. And by talcum powder 7 products, let's be clear as to what we 8 are talking about. We are talking about 9 products like Johnson's Baby Powder. 10 A. Okay. 11 Q. Okay. And Shower to Shower. 12 A. Mm-hmm. 13 Q. Okay. You know what those 14 products are, correct? 15 A. I'm aware of them, yes. 16 Q. Okay. And before we get to 17 discussing your specific contributions to 18 the science related to the question of 19 whether or not talcum powder products 20 cause ovarian cancer, I want to ask you a 21 pretty -- a series of questions which I 22 think are pretty straightforward. Okay. 23 Number one, whether or not 24 talcum powder products can cause or</p>

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<p style="text-align: right;">Page 38</p> <p>1 contribute to the development of ovarian 2 cancer is not a new question, is it? 3 MR. HEGARTY: Objection to 4 form. 5 THE WITNESS: Can you 6 specify, is not a new question? 7 BY MR. TISI: 8 Q. It is a question that has 9 been studied since at least the 1970s and 10 '80s. 11 MR. HEGARTY: Objection to 12 form. 13 THE WITNESS: There have 14 been epidemiologic studies 15 starting since -- I can't remember 16 the exact date, but it has gone 17 back a couple decades. 18 BY MR. TISI: 19 Q. Okay. Second, the question 20 has been debated amongst epidemiologists 21 for decades? 22 MR. HUDSON: Objection to 23 form. 24 THE WITNESS: Has it been</p>	<p style="text-align: right;">Page 40</p> <p>1 Q. You know that that's his 2 view, correct? 3 A. I don't know for certain, 4 okay. I know he's been in talc 5 litigation. I haven't listened to 6 anything he said. I don't -- I don't 7 remember. I assume that's his view. 8 Q. Okay. 9 A. Okay. 10 Q. Okay. So my question is, 11 and I'm not trying to -- to dance around 12 here. 13 A. Okay. 14 Q. This has been an issue in 15 which people, epidemiologists, have 16 differed about the quality and quantity 17 of the evidence that support or doesn't 18 support that question, correct? 19 MR. HEGARTY: Objection to 20 form. 21 MR. HUDSON: Objection to 22 form. 23 THE WITNESS: There have 24 been some published meta-analyses</p>
<p style="text-align: right;">Page 39</p> <p>1 debated among epidemiologists for 2 decades. You have to give me like 3 specific examples. 4 BY MR. TISI: 5 Q. Do you know who Daniel 6 Cramer is? 7 A. Yeah, I know who he is. 8 Q. Okay. He's taken the 9 position that he -- that talcum powder 10 products are likely a carcinogen, 11 correct? 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: I haven't seen 15 him make that statement. 16 BY MR. TISI: 17 Q. You know that's his view, 18 correct? 19 MR. HEGARTY: Same 20 objection. 21 THE WITNESS: I -- I have 22 not seen a publication where he's 23 made that statement. 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 41</p> <p>1 on the topic throughout the years, 2 that's correct. 3 BY MR. TISI: 4 Q. Okay. And some -- well, 5 that wasn't my question. 6 A. Okay. 7 Q. My question was, that -- 8 that within the epidemiology community, 9 epidemiologists have -- differ as to the 10 quantity and quality of the evidence that 11 supports or disputes the question about 12 whether or not ovarian cancer can be 13 caused by talcum powder products? 14 MR. HUDSON: Objection to 15 form. 16 THE WITNESS: You are 17 talking about the epidemiology 18 community, would that be referring 19 to the IARC monograph? 20 BY MR. TISI: 21 Q. For example. I'm talking 22 about just in general, there has been a 23 debate in the epidemiology community. 24 MR. HEGARTY: Objection to</p>

11 (Pages 38 to 41)



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<p style="text-align: right;">Page 42</p> <p>1 form.</p> <p>2 THE WITNESS: I can't really</p> <p>3 answer that. It seems like a</p> <p>4 general question.</p> <p>5 BY MR. TISI:</p> <p>6 Q. It is a general question.</p> <p>7 A. Yeah.</p> <p>8 Q. Who -- I'm not asking about</p> <p>9 who or what. I'm asking has there been a</p> <p>10 debate in the scientific community over</p> <p>11 the past 20, 30 years about the quality</p> <p>12 and quantity of evidence that supports or</p> <p>13 does not support the issue of whether or</p> <p>14 not talcum powder products are capable of</p> <p>15 causing ovarian cancer?</p> <p>16 MR. HUDSON: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: There have</p> <p>19 been a number of studies that have</p> <p>20 been done. And so in each of</p> <p>21 those studies, the authors of</p> <p>22 those studies have kind of</p> <p>23 evaluated their own conclusions</p> <p>24 and discussed them.</p>	<p style="text-align: right;">Page 44</p> <p>1 debate process.</p> <p>2 A. Okay.</p> <p>3 Q. I'm talking about in a</p> <p>4 general sense, Doctor.</p> <p>5 A. Okay. I've written my --</p> <p>6 Q. Let me just stop the</p> <p>7 question.</p> <p>8 A. Okay.</p> <p>9 Q. I'm not going to play word</p> <p>10 games with you, okay?</p> <p>11 A. Yes, okay.</p> <p>12 Q. You understand that the</p> <p>13 scientific -- when we talk about</p> <p>14 scientific debate. I'm not talking about</p> <p>15 two people standing at a lectern debating</p> <p>16 like we see in the presidential primary.</p> <p>17 A. Okay.</p> <p>18 Q. Okay. I'm talking about,</p> <p>19 the scientific community oftentimes</p> <p>20 debates questions, correct?</p> <p>21 MR. HEGARTY: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: Yes.</p> <p>24 BY MR. TISI:</p>
<p style="text-align: right;">Page 43</p> <p>1 They may have discussed them</p> <p>2 with respect to how their findings</p> <p>3 differ or are the same from</p> <p>4 previous studies. So that's</p> <p>5 just -- that's just common. You</p> <p>6 always do that in science. You</p> <p>7 discuss your findings in</p> <p>8 relationship to other findings. I</p> <p>9 wouldn't necessarily call it a</p> <p>10 debate. I would call it a -- an</p> <p>11 evaluation of the data.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Okay. And you don't think</p> <p>14 that there have been -- okay. We'll keep</p> <p>15 moving.</p> <p>16 Third, have you been part of</p> <p>17 that debate over the past 20, 30 years?</p> <p>18 MR. SILVER: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: So I have -- I</p> <p>21 have not been in a debate</p> <p>22 process --</p> <p>23 BY MR. TISI:</p> <p>24 Q. I'm not asking about a</p>	<p style="text-align: right;">Page 45</p> <p>1 Q. And they do it in several</p> <p>2 ways. They do it through published</p> <p>3 literature, correct?</p> <p>4 A. Yes.</p> <p>5 Q. They do it at meetings,</p> <p>6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. Sometimes they do it at</p> <p>9 formal meetings like IARC, for example?</p> <p>10 A. That's correct.</p> <p>11 Q. All right. Okay. So with</p> <p>12 that in mind, does -- have you been part</p> <p>13 of the general debate about whether or</p> <p>14 not talcum powder products cause ovarian</p> <p>15 cancer?</p> <p>16 MR. HUDSON: Objection to</p> <p>17 form.</p> <p>18 MR. HEGARTY: Objection to</p> <p>19 form.</p> <p>20 MR. SILVER: Objection to</p> <p>21 form, asked and answered.</p> <p>22 THE WITNESS: I have written</p> <p>23 on the topic, okay. I wouldn't</p> <p>24 say I've been part of a debate.</p>

12 (Pages 42 to 45)



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<p style="text-align: right;">Page 46</p> <p>1 I've never debated anyone. I know</p> <p>2 you don't want to use that term.</p> <p>3 But I have written on it,</p> <p>4 that's -- that's correct. I've</p> <p>5 expressed my views on it.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Okay. Fourth, have you been</p> <p>8 paid by the defendants and their lawyers</p> <p>9 directly and indirectly to write medical</p> <p>10 articles and do epidemiology studies?</p> <p>11 MR. HEGARTY: Objection to</p> <p>12 form.</p> <p>13 MR. SILVER: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: No.</p> <p>16 BY MR. TISI:</p> <p>17 Q. You have not had any of your</p> <p>18 published literature supported by any of</p> <p>19 the defendants around this table?</p> <p>20 MR. HEGARTY: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: That's</p> <p>23 correct.</p> <p>24 BY MR. TISI:</p>	<p style="text-align: right;">Page 48</p> <p>1 answered.</p> <p>2 MR. SILVER: You are asking</p> <p>3 three different questions.</p> <p>4 THE WITNESS: So the answer</p> <p>5 is no.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Okay. Have the defendants</p> <p>8 in this case -- let's take them one at a</p> <p>9 time.</p> <p>10 Has Johnson &amp; Johnson been</p> <p>11 given the opportunity to look at your</p> <p>12 articles and edit them or make comments</p> <p>13 to them before they were published?</p> <p>14 MR. HEGARTY: Objection to</p> <p>15 form.</p> <p>16 BY MR. TISI:</p> <p>17 Q. Any of your articles on</p> <p>18 talc?</p> <p>19 A. No.</p> <p>20 Q. Never?</p> <p>21 A. Well, which articles are you</p> <p>22 talking about?</p> <p>23 Q. I said any. Any of your</p> <p>24 articles on talc. Have -- has Johnson &amp;</p>
<p style="text-align: right;">Page 47</p> <p>1 Q. Okay. And I said directly</p> <p>2 and indirectly.</p> <p>3 A. Yes.</p> <p>4 Q. And you and your colleagues,</p> <p>5 you and your colleagues have not received</p> <p>6 any money whatsoever for the publication</p> <p>7 for example, of your meta-analysis on</p> <p>8 diaphragms?</p> <p>9 MR. HEGARTY: Objection to</p> <p>10 form.</p> <p>11 MR. HUDSON: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: So there's two</p> <p>14 questions. Me myself or me and my</p> <p>15 colleagues?</p> <p>16 BY MR. TISI:</p> <p>17 Q. I'm asking you whether or</p> <p>18 not you received money as from the</p> <p>19 defendants, directly or indirectly, with</p> <p>20 respect to your research or publications</p> <p>21 on talcum powder products and ovarian</p> <p>22 cancer.</p> <p>23 MR. SILVER: Objection.</p> <p>24 MR. HEGARTY: Asked and</p>	<p style="text-align: right;">Page 49</p> <p>1 Johnson been given the opportunity,</p> <p>2 either informally or pursuant to any</p> <p>3 contracts, to review your article or</p> <p>4 articles before they were published?</p> <p>5 MR. HEGARTY: Objection to</p> <p>6 form, asked and answered.</p> <p>7 THE WITNESS: For my</p> <p>8 published articles, no.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Okay. How about Imerys,</p> <p>11 directly or indirectly, were they able to</p> <p>12 look at your medical articles and comment</p> <p>13 on them before they were published?</p> <p>14 MR. SILVER: Objection to</p> <p>15 form.</p> <p>16 THE WITNESS: For my</p> <p>17 published articles, no.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Okay. Never?</p> <p>20 A. Never.</p> <p>21 Q. Not -- their lawyers never</p> <p>22 had an opportunity to redline any of your</p> <p>23 articles?</p> <p>24 A. My published articles? No.</p>



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<p style="text-align: right;">Page 50</p> <p>1 Q. Okay. What about PCPC, did 2 they ever have an opportunity, before any 3 of your articles were published, to edit 4 them? 5 A. None of my published 6 articles in peer-reviewed journals have 7 been edited by anybody. 8 Q. Okay. What about -- now 9 you've done some reports, right, for the 10 FDA for example, and you mentioned the 11 National Toxicology Program. You issued 12 reports for those organizations, correct? 13 MR. HEGARTY: Objection to 14 form. 15 THE WITNESS: I did a report 16 for The Weinberg Group that was 17 submitted to the NTP. 18 BY MR. TISI: 19 Q. And you also participated in 20 drafting a response to comments for a 21 Citizen's Petition to get a warning put 22 on talc that talcum powder products may 23 cause ovarian cancer, do you remember 24 that?</p>	<p style="text-align: right;">Page 52</p> <p>1 It might have been, but 2 you'd have to ask Dr. Huncharek 3 that because I have no knowledge 4 of it. 5 BY MR. TISI: 6 Q. Well, let me ask you. Do 7 you know -- when was the last time you 8 spoke to Dr. Huncharek? 9 A. A couple months ago. 10 Q. Do you know where he is? 11 A. He lives in South Carolina. 12 Q. Okay. We'll talk about this 13 in a moment. But you know that he's been 14 a fugitive from -- that -- that law 15 enforcement has been looking for 16 Dr. Huncharek? 17 MR. HEGARTY: Objection to 18 form. 19 THE WITNESS: I have no 20 knowledge of that. 21 BY MR. TISI: 22 Q. You don't know that at all? 23 A. No. 24 Q. Do you know that he claims</p>
<p style="text-align: right;">Page 51</p> <p>1 A. That's correct. 2 Q. Okay. And so you wrote a 3 report on that with Dr. Huncharek, 4 correct? 5 A. A report was written, right. 6 Q. Right. Well, a report was 7 written. You wrote it, right? 8 A. I actually didn't write the 9 report. 10 Q. Did you sign your name to 11 the report? 12 A. I did. 13 Q. Okay. Did you -- was that 14 report edited at all, were either of 15 those reports given to the defendants to 16 edit or review before it was submitted to 17 either the NTP or the FDA? 18 MR. HUDSON: Objection to 19 form. 20 MR. HEGARTY: Objection to 21 form. 22 THE WITNESS: Was the 23 report, the FDA, the Citizen's 24 Petition report edited?</p>	<p style="text-align: right;">Page 53</p> <p>1 that all his documents related to the 2 publications of your -- and the 3 Meta-Analysis Research Group which is the 4 organization that sponsored some of the 5 publications, have burned to the ground? 6 MR. HEGARTY: Objection to 7 form. 8 MR. HUDSON: Objection to 9 form. 10 THE WITNESS: I'm not 11 familiar with that. 12 BY MR. TISI: 13 Q. Do you know a Dr. Geschwind? 14 A. That name sounds -- what's 15 the first name? 16 Q. I don't know the name. But 17 you published articles with a 18 Dr. Geschwind, correct, out of Johns 19 Hopkins? 20 A. Dr. Geschwind. I'd have to 21 see it. I don't recall. 22 Q. Do you know -- do you know 23 the 2003 meta-analysis from -- that 24 Dr. Huncharek published on ovarian cancer</p>

14 (Pages 50 to 53)



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<p style="text-align: right;">Page 54</p> <p>1 and talc?</p> <p>2 A. I am familiar with that,</p> <p>3 yes.</p> <p>4 Q. Dr. Geschwind was a</p> <p>5 co-author of that. Have you heard that</p> <p>6 Dr. Geschwind is in jail because, because</p> <p>7 he stole about \$500,000 from Johns</p> <p>8 Hopkins University? Have you ever heard</p> <p>9 of that?</p> <p>10 MR. HEGARTY: Objection to</p> <p>11 form.</p> <p>12 THE WITNESS: No, not</p> <p>13 really.</p> <p>14 BY MR. TISI:</p> <p>15 Q. The reports that were</p> <p>16 submitted to regulators like the NTP and</p> <p>17 the FDA with your name on it, they were</p> <p>18 paid for by the defendants, were they</p> <p>19 not?</p> <p>20 MR. HEGARTY: Objection.</p> <p>21 MR. HUDSON: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: I'm sorry, can</p> <p>24 you repeat that, please?</p>	<p style="text-align: right;">Page 56</p> <p>1 hired by the industry, in fact, to write</p> <p>2 that report, correct?</p> <p>3 MR. HUDSON: Objection to</p> <p>4 form.</p> <p>5 MR. HEGARTY: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: No. The only</p> <p>8 thing I know is that I was hired</p> <p>9 by The Weinberg Group. That's</p> <p>10 what I knew.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Okay. That's what you knew?</p> <p>13 A. Right.</p> <p>14 Q. You know differently now,</p> <p>15 right?</p> <p>16 MR. HEGARTY: Objection to</p> <p>17 form.</p> <p>18 BY MR. TISI:</p> <p>19 Q. You know you were hired by</p> <p>20 the industry to file a report by the --</p> <p>21 to the NTP, correct?</p> <p>22 MR. HEGARTY: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: I don't know</p>
<p style="text-align: right;">Page 55</p> <p>1 BY MR. TISI:</p> <p>2 Q. Yeah. I'm going to talk</p> <p>3 about this in more detail in a moment.</p> <p>4 A. Yeah.</p> <p>5 Q. Number one, the report that</p> <p>6 you submitted in 2000 to the NTP through</p> <p>7 The Weinberg Group.</p> <p>8 A. Yes.</p> <p>9 Q. Was that -- do you know</p> <p>10 whether that was paid for by the</p> <p>11 defendants in this case?</p> <p>12 A. It was paid for by The</p> <p>13 Weinberg Group.</p> <p>14 Q. Okay. And you don't -- you</p> <p>15 don't have any understanding that the --</p> <p>16 you know, The Weinberg Group was hired by</p> <p>17 the CTFA, the Cosmetic Toiletry and</p> <p>18 Fragrance Association that represents</p> <p>19 talc -- cosmetic talc manufacturers?</p> <p>20 A. Yes.</p> <p>21 MR. HUDSON: Objection to</p> <p>22 form.</p> <p>23 BY MR. TISI:</p> <p>24 Q. So you know that you were</p>	<p style="text-align: right;">Page 57</p> <p>1 that for certain. It's not</p> <p>2 something that I've thought about.</p> <p>3 I was hired by The Weinberg Group.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Oh. You never thought about</p> <p>6 it. Doctor, you were named as an expert</p> <p>7 in litigation and you don't know what</p> <p>8 your involvement was with the NTP?</p> <p>9 MR. HUDSON: Objection to</p> <p>10 form.</p> <p>11 MR. HEGARTY: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: I can only</p> <p>14 tell you what happened. I was</p> <p>15 hired by The Weinberg Group to</p> <p>16 submit a document to the NTP.</p> <p>17 That's what I did.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Okay. Now, throughout the</p> <p>20 decades you have been writing on the</p> <p>21 subject of talc and ovarian cancer. You</p> <p>22 have taken a fairly consistent position,</p> <p>23 as far as I can tell, that while there is</p> <p>24 evidence of an epidemiologic association</p>

15 (Pages 54 to 57)



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<p style="text-align: right;">Page 58</p> <p>1 seen in some studies, you do not believe</p> <p>2 that that evidence supports a causal</p> <p>3 inference.</p> <p>4 A. That's correct.</p> <p>5 MR. HEGARTY: Objection to</p> <p>6 form.</p> <p>7 BY MR. TISI:</p> <p>8 Q. Have you and I ever met, by</p> <p>9 the way?</p> <p>10 A. No.</p> <p>11 Q. Okay. You are represented</p> <p>12 by a lawyer today, Mr. Hudson?</p> <p>13 A. That's correct.</p> <p>14 Q. Okay. And he's your lawyer</p> <p>15 for this deposition, right?</p> <p>16 A. That's correct.</p> <p>17 Q. Okay. But when is the first</p> <p>18 time you and Mr. Hudson actually met or</p> <p>19 spoke on the phone?</p> <p>20 A. It was in the early August.</p> <p>21 I'm sorry, first time we met was early</p> <p>22 August. I'd spoken with him back in</p> <p>23 November.</p> <p>24 Q. Right. Are you paying for</p>	<p style="text-align: right;">Page 60</p> <p>1 BY MR. TISI:</p> <p>2 Q. And you have spoken with her</p> <p>3 on the phone, correct?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. Going back 10,</p> <p>6 15 years, correct?</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: Not that long</p> <p>10 ago.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Not that long ago.</p> <p>13 A. 2000 -- I think it was 2010.</p> <p>14 Q. Okay. We'll talk about that</p> <p>15 in relationship to the entries on your</p> <p>16 privilege log that we just talked about.</p> <p>17 Before 2018, you were</p> <p>18 represented by the lawyers, by the</p> <p>19 Johnson &amp; Johnson lawyers in litigation</p> <p>20 involving women like my clients who claim</p> <p>21 that talc caused or contributed to their</p> <p>22 ovarian cancer, correct?</p> <p>23 MR. HUDSON: Objection to</p> <p>24 form.</p>
<p style="text-align: right;">Page 59</p> <p>1 Mr. Hudson's time?</p> <p>2 A. No.</p> <p>3 Q. Do you know who is?</p> <p>4 A. Johnson &amp; Johnson.</p> <p>5 Q. And, in fact, sitting next</p> <p>6 to Johnson &amp; Johnson is Mr. Hegarty?</p> <p>7 A. That's correct.</p> <p>8 Q. And Mr. --</p> <p>9 MR. HEGARTY: Mr. Hudson.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Before this past year, you</p> <p>12 had met Mr. Hegarty on numerous</p> <p>13 occasions, correct?</p> <p>14 A. That's correct.</p> <p>15 Q. Okay. And you know his</p> <p>16 colleague Ms. Frazier?</p> <p>17 A. Yes.</p> <p>18 Q. And you met with Ms. Frazier</p> <p>19 on numerous occasions going back years,</p> <p>20 correct?</p> <p>21 MR. HEGARTY: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: I have met her</p> <p>24 several times.</p>	<p style="text-align: right;">Page 61</p> <p>1 THE WITNESS: I don't know</p> <p>2 who your clients are.</p> <p>3 BY MR. TISI:</p> <p>4 Q. Okay. And when I say the</p> <p>5 word talc, I just want to be clear. For</p> <p>6 the purpose of this deposition, I'm</p> <p>7 talking about talcum powder products.</p> <p>8 Okay. Things like Johnson &amp; Johnson Baby</p> <p>9 Powder. Okay?</p> <p>10 A. Mm-hmm.</p> <p>11 Q. I'm not talking about pure</p> <p>12 granular talc.</p> <p>13 A. Okay.</p> <p>14 Q. Okay. I'm talking about</p> <p>15 what comes in the bottle that you can</p> <p>16 walk into Walmart and pick off the</p> <p>17 shelves, okay?</p> <p>18 A. Yes.</p> <p>19 Q. So unless I say otherwise,</p> <p>20 if I use the word talc, I mean talcum</p> <p>21 powder products, cosmetic talc.</p> <p>22 A. Okay. Okay.</p> <p>23 Q. Okay. Now, in those other</p> <p>24 cases, you were put out as an expert</p>



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<p style="text-align: right;">Page 62</p> <p>1 hired by Johnson &amp; Johnson, correct?</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 THE WITNESS: I'm sorry,</p> <p>5 which cases?</p> <p>6 BY MR. TISI:</p> <p>7 Q. Any prior cases that you</p> <p>8 were involved with. You were an expert</p> <p>9 for Johnson &amp; Johnson?</p> <p>10 A. On talc product cases.</p> <p>11 MR. HEGARTY: Objection.</p> <p>12 THE WITNESS: Yes.</p> <p>13 MR. SILVER: Chris, can we</p> <p>14 take a -- stop for a second.</p> <p>15 THE VIDEOGRAPHER: Going off</p> <p>16 the record, 10:17 a.m.</p> <p>17 (Short break.)</p> <p>18 THE VIDEOGRAPHER: We are</p> <p>19 back on record. The time is</p> <p>20 10:22 a.m.</p> <p>21 BY MR. TISI:</p> <p>22 Q. So we're talking about your</p> <p>23 relationship with Shook Hardy &amp; Bacon.</p> <p>24 Mr. Hegarty, some of his colleagues</p>	<p style="text-align: right;">Page 64</p> <p>1 the answer would be derived from</p> <p>2 information that you learned from</p> <p>3 counsel.</p> <p>4 MR. TISI: No, counsel.</p> <p>5 He's entitled to answer what his</p> <p>6 understanding is. He's not</p> <p>7 allowed to reveal your -- your</p> <p>8 direct communications.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Do you understand, if you're</p> <p>11 testifying here today, that your</p> <p>12 relationship with Shook Hardy &amp; Bacon</p> <p>13 didn't start on litigation issues</p> <p>14 after -- until after 2010, any document</p> <p>15 that would be listed on your privilege</p> <p>16 log as listing Shook Hardy &amp; Bacon prior</p> <p>17 to 2010 would not be involved in</p> <p>18 litigation, correct?</p> <p>19 MR. SILVER: Objection to</p> <p>20 form.</p> <p>21 MR. HUDSON: Objection to</p> <p>22 form and the same instruction,</p> <p>23 Dr. Muscat.</p> <p>24 THE WITNESS: I turned over</p>
<p style="text-align: right;">Page 63</p> <p>1 including Ms. Frazier.</p> <p>2 For the past 20 years or</p> <p>3 more have you been communicating with</p> <p>4 Shook Hardy &amp; Bacon about issues relating</p> <p>5 to litigation involving talc?</p> <p>6 MR. HEGARTY: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: 20 years, no.</p> <p>9 It's been about eight years.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Okay. Eight years from --</p> <p>12 that would have been 2010?</p> <p>13 A. Sounds about right.</p> <p>14 Q. And so any documents that</p> <p>15 would be listed on your privilege log as</p> <p>16 being related to Shook Hardy &amp; Bacon</p> <p>17 before 2010 would not be in any way</p> <p>18 involved in litigation?</p> <p>19 MR. HEGARTY: Objection to</p> <p>20 form.</p> <p>21 MR. HUDSON: Objection to</p> <p>22 form.</p> <p>23 And, Dr. Muscat, I'm going</p> <p>24 to instruct you not to answer if</p>	<p style="text-align: right;">Page 65</p> <p>1 whatever documents were asked of</p> <p>2 me.</p> <p>3 BY MR. TISI:</p> <p>4 Q. Well, for example, if you</p> <p>5 look at the very first -- look at the</p> <p>6 very first entry on this sheet here, it</p> <p>7 lists Shook Hardy &amp; Bacon, 1982,</p> <p>8 materials provided by outside counsel in</p> <p>9 connection with ongoing litigation. Were</p> <p>10 you working on litigation with Shook</p> <p>11 Hardy &amp; Bacon in 1982?</p> <p>12 A. No.</p> <p>13 Q. So that would be wrong,</p> <p>14 correct?</p> <p>15 MR. HUDSON: Objection,</p> <p>16 form.</p> <p>17 MR. HEGARTY: Objection,</p> <p>18 counsel. You know that that is</p> <p>19 not referring to communication --</p> <p>20 direct communication with Shook</p> <p>21 Hardy &amp; Bacon by the way that the</p> <p>22 privileged is described.</p> <p>23 MR. TISI: Author from</p> <p>24 materials provided by outside</p>

17 (Pages 62 to 65)



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<p>1 counsel in connection with ongoing 2 litigation. 3 MR. HEGARTY: Right. 4 Materials provided by outside 5 counsel in connection with ongoing 6 litigation dated in 1982. 7 MR. TISI: Correct. 8 MR. HUDSON: Right. 9 MR. HEGARTY: So it doesn't 10 mean that the communication was 11 back in 1982. 12 MR. TISI: You mean to tell 13 me the dates here do not reflect 14 the dates of the communication? 15 MR. HEGARTY: I didn't 16 prepare the privilege log. But as 17 I read this, the description is 18 referring to the document itself. 19 MR. TISI: And the date of 20 the document would be August of 21 1982. 22 MR. HEGARTY: Would be the 23 date of the material that was 24 provided by outside counsel in</p>	<p>1 Q. Okay. My question is, did 2 you have -- if this column is correct, 3 that is a 1982 document, correct? 4 MR. HEGARTY: Objection to 5 form. 6 THE WITNESS: I didn't 7 prepare this so I can't -- but if 8 you ask me a more general 9 question, then -- 10 BY MR. TISI: 11 Q. The more general question 12 is, did you receive documents from Shook 13 Hardy &amp; Bacon prior to 19 -- prior to 14 2010? 15 MR. HUDSON: Objection to 16 form. 17 MR. HEGARTY: Objection to 18 form. 19 BY MR. TISI: 20 Q. Any documents at all? 21 A. Not to my knowledge. 22 Q. Did you communicate with 23 Shook Hardy &amp; Bacon prior to 2010? 24 A. Not to my knowledge.</p>
Page 67	Page 69
<p>1 connection with ongoing 2 litigation. 3 MR. TISI: The date of the 4 document. 5 MR. HEGARTY: Correct. 6 MR. TISI: Right. 7 BY MR. TISI: 8 Q. So did you receive documents 9 in contact, in 1982 on ongoing 10 litigation? 11 MR. HEGARTY: Recognizing 12 that you can get documents back in 13 1982 in 2018. 14 MR. TISI: That's not -- 15 that's not what this column is 16 for. 17 MR. HEGARTY: Well, I 18 disagree. 19 MR. TISI: The column is 20 for -- is for -- okay. 21 MR. HEGARTY: I also think 22 it's improper to ask Dr. Muscat to 23 answer legal questions. 24 BY MR. TISI:</p>	<p>1 Q. And if these documents on 2 the privilege log are before 2010, they 3 would have been before that relationship, 4 correct? 5 MR. HEGARTY: Objection to 6 form. 7 MR. HUDSON: Objection to 8 form. 9 THE WITNESS: I assume so. 10 BY MR. TISI: 11 Q. I'd like to show you your 12 CV. I put it up on the screen. But I 13 also gave you a copy. 14 Now, the data that we've 15 been provided for this document, 16 Exhibit 1, indicates that it was updated 17 in July of 2018. The metadata that was 18 provided to us. 19 A. Okay. 20 Q. Did you update this CV in 21 2018? 22 A. So this might have been 23 updated. I update my CV regularly. 24 Q. Okay. When you update your</p>



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<p style="text-align: right;">Page 70</p> <p>1 CV, do you sometimes exclude things that</p> <p>2 had previously been there?</p> <p>3 A. It depends on the nature of</p> <p>4 the CV.</p> <p>5 You know, the -- when</p> <p>6 someone asks for a CV, it could come in</p> <p>7 different formats. So actually you do</p> <p>8 include and exclude things. It depends</p> <p>9 on what people are asking for.</p> <p>10 Q. Okay. So do you have</p> <p>11 different CVs that you use for different</p> <p>12 purposes?</p> <p>13 A. Yes.</p> <p>14 Q. Do you have CVs that you use</p> <p>15 in connection with your consulting as an</p> <p>16 expert or consultant on issues related to</p> <p>17 epidemiology?</p> <p>18 MR. HEGARTY: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: I usually use</p> <p>21 my academic CV. That's the CV</p> <p>22 that I normally use for -- not all</p> <p>23 the time, but if it's outside of</p> <p>24 an academic purpose, I'll often</p>	<p style="text-align: right;">Page 72</p> <p>1 THE WITNESS: For me</p> <p>2 personally, it's almost hard to</p> <p>3 answer that question. The CVs are</p> <p>4 updated regularly. So every time</p> <p>5 you get a paper published, you</p> <p>6 update that.</p> <p>7 So just that in terms alone,</p> <p>8 the publication list tends to</p> <p>9 change.</p> <p>10 BY MR. TISI:</p> <p>11 Q. That's not my question.</p> <p>12 A. Okay.</p> <p>13 Q. I understand that as time</p> <p>14 goes on you may add.</p> <p>15 A. Right.</p> <p>16 Q. Right. My question is, do</p> <p>17 you have CVs that you use for different</p> <p>18 purposes, and a CV, for the record, is</p> <p>19 basically your professional resumé,</p> <p>20 correct?</p> <p>21 A. Mm-hmm. Mm-hmm.</p> <p>22 Q. Right? And you might have a</p> <p>23 CV that you use for obtaining a grant. A</p> <p>24 CV that you use for consulting with</p>
<p style="text-align: right;">Page 71</p> <p>1 use the academic CV.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Well, what other kinds of</p> <p>4 CVs do you have, Doctor?</p> <p>5 A. So, it's -- well, even -- if</p> <p>6 you really want to hear it. I mean even</p> <p>7 the academic CV is, it's something that</p> <p>8 changes constantly. And there are</p> <p>9 reasons for that.</p> <p>10 Do you want to hear it?</p> <p>11 Q. Well, what I really want to</p> <p>12 know actually is -- I kind of do. But</p> <p>13 let me just get to the question.</p> <p>14 A. Okay.</p> <p>15 Q. I've got a lot of ground to</p> <p>16 cover.</p> <p>17 A. Okay.</p> <p>18 Q. Are there categories of</p> <p>19 information that you include in your --</p> <p>20 in CVs that you use for some purposes</p> <p>21 that are not in CVs that you use for</p> <p>22 other purposes?</p> <p>23 MR. HUDSON: Objection to</p> <p>24 form.</p>	<p style="text-align: right;">Page 73</p> <p>1 defendants as an expert. A CV you may</p> <p>2 use for a different purposes.</p> <p>3 Okay. Do you have CVs that</p> <p>4 you use for different purposes?</p> <p>5 MR. HEGARTY: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: So, yes.</p> <p>8 BY MR. TISI:</p> <p>9 Q. Okay. And so the CVs that</p> <p>10 you use for consulting, does it contain</p> <p>11 categories of information that are not</p> <p>12 contained on the academic CV that you</p> <p>13 provided to us?</p> <p>14 A. I have not been asked for a</p> <p>15 consulting CV in a long time.</p> <p>16 Q. Okay. I didn't ask that</p> <p>17 question.</p> <p>18 A. Yes.</p> <p>19 Q. Okay? You're going to have</p> <p>20 to listen to my questions, okay, or else</p> <p>21 we're never going to get done here.</p> <p>22 My question is, are they</p> <p>23 categories of information that you use on</p> <p>24 your consulting CVs that do not appear on</p>

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<p style="text-align: right;">Page 74</p> <p>1 your academic CVs, like what we've had 2 marked here as Exhibit Number 1? 3 A. Categories of information 4 that are on my consulting. No, I don't 5 think so. 6 Q. Okay. So you don't include 7 for example, a section on other companies 8 that you may have worked for, or 9 consulting that you have done? 10 A. If you're asking me whether 11 I put down my work with Shook Hardy &amp; 12 Bacon, if that's on my CV? 13 Q. I didn't ask you that. 14 A. Okay. 15 Q. Okay. You're going to have 16 to listen to my questions. 17 A. You said other categories. 18 Q. Are there categories for 19 example, of consulting for example, where 20 you list consulting activities? 21 A. Generally not. 22 Q. Okay. 23 A. Okay. 24 Q. And have -- do you have a CV</p>	<p style="text-align: right;">Page 76</p> <p>1 Q. Okay. And so I asked you 2 whether or not you have different CVs 3 that you use for different purposes that 4 have different categories. This might be 5 one kind of category that you include in 6 your nonacademic CV, correct? 7 MR. HUDSON: Objection to 8 form. 9 THE WITNESS: The -- that's 10 what I listed back in 2005, that's 11 correct. 12 BY MR. TISI: 13 Q. Right. All right. And so 14 at that time, you listed The Weinberg 15 Group, correct? 16 A. That's correct. 17 Q. And Crowell &amp; Moring, 18 correct? 19 A. That's correct. 20 Q. Okay. Weinberg Group we 21 know was hired by the PCPC, correct? 22 A. That's correct. 23 MR. LOCKE: Objection to 24 form.</p>
<p style="text-align: right;">Page 75</p> <p>1 that actually lists your consulting 2 activities that is not Exhibit Number 1? 3 A. A CV that lists my 4 consulting activities. No. 5 Q. I'm going to show you 6 Exhibit Number 4. 7 (Document marked for 8 identification as Exhibit 9 Muscat-4.) 10 BY MR. TISI: 11 Q. Which is a CV that I pulled 12 from your work with Johnson &amp; Johnson 13 from -- actually from Imerys, in 2005. 14 And you'll see, if you go down, it has a 15 section entitled Consulting Activities. 16 Do you see that? 17 A. I do see that. 18 Q. Okay. That is your CV from 19 2005, correct? 20 A. Yes. 21 Q. This is a category that is 22 not listed on your academic CV that you 23 provided to us in 2018, is that right? 24 A. That's correct.</p>	<p style="text-align: right;">Page 77</p> <p>1 BY MR. TISI: 2 Q. And that refers -- sorry. 3 And that refers to your work on behalf of 4 the -- providing a report to the National 5 Toxicology Program or NTP, on talc? 6 MR. HUDSON: Objection to 7 form. 8 THE WITNESS: That's 9 correct. 10 BY MR. TISI: 11 Q. And Crowell &amp; Moring is the 12 law firm for Imerys, correct? 13 A. I don't know whether they're 14 still the law firm for Imerys or not. 15 They were in the past. 16 Q. I'm sorry? 17 A. I said I still don't know -- 18 I don't know as of the moment. 19 Q. You don't know whether or 20 not Crowell &amp; Moring was the law firm -- 21 A. At the moment. For Imerys. 22 Q. I didn't ask you at the 23 moment. 24 A. Okay.</p>

20 (Pages 74 to 77)



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<p>1 Q. I asked you --</p> <p>2 A. Okay.</p> <p>3 Q. -- you know Crowell &amp; Moring</p> <p>4 is a law firm that represented Imerys on</p> <p>5 talc-related issues.</p> <p>6 MR. HEGARTY: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: That's</p> <p>9 correct.</p> <p>10 BY MR. TISI:</p> <p>11 Q. And you did consulting</p> <p>12 activities for them in 2005.</p> <p>13 MR. HUDSON: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: Okay.</p> <p>16 BY MR. TISI:</p> <p>17 Q. Is that true?</p> <p>18 MR. HEGARTY: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: I met with</p> <p>21 Crowell &amp; Moring, that's correct.</p> <p>22 BY MR. TISI:</p> <p>23 Q. I didn't ask you that. I</p> <p>24 asked you whether you did -- you and I</p>	<p>1 form.</p> <p>2 THE WITNESS: I'd have to go</p> <p>3 through the whole thing and</p> <p>4 compare them.</p> <p>5 BY MR. TISI:</p> <p>6 Q. I'm not asking you to</p> <p>7 compare them. Just since 2005, have you</p> <p>8 done -- we know you've done expert work</p> <p>9 for litigation, for Shook Hardy &amp; Bacon,</p> <p>10 representing them in talc suits, correct?</p> <p>11 MR. HEGARTY: Objection to</p> <p>12 form.</p> <p>13 MR. HUDSON: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: I've worked</p> <p>16 with Shook Hardy &amp; Bacon, that's</p> <p>17 correct.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Other than that, have you</p> <p>20 had other consulting with the defendants</p> <p>21 in this case on talc-related issues?</p> <p>22 A. So, yes. There was a</p> <p>23 meeting I went to at Johnson &amp; Johnson</p> <p>24 for the Citizen's Petition, that's</p>
Page 79	Page 81
<p>1 met each other, correct?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. We are not -- you are</p> <p>4 not my consultant, are you?</p> <p>5 A. No.</p> <p>6 Q. Okay. One of your</p> <p>7 consulting activities were for the</p> <p>8 lawyers of -- for Imerys, correct?</p> <p>9 MR. HEGARTY: Objection to</p> <p>10 form.</p> <p>11 THE WITNESS: Correct.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Doctor, I didn't think I was</p> <p>14 going to have to fight you on this. It's</p> <p>15 on your CV, correct?</p> <p>16 A. Yes. Yes, that's correct.</p> <p>17 Q. But it's not on your current</p> <p>18 CV?</p> <p>19 A. That's correct.</p> <p>20 Q. Are there any other</p> <p>21 consulting activities from 2005 that are</p> <p>22 not listed on your academic CV that</p> <p>23 you've done for the talc industry?</p> <p>24 MR. HEGARTY: Objection to</p>	<p>1 correct.</p> <p>2 Q. And you met with them to</p> <p>3 propose additional studies with</p> <p>4 Dr. Huncharek?</p> <p>5 A. That's correct.</p> <p>6 Q. And you had phone calls with</p> <p>7 them, correct?</p> <p>8 MR. HEGARTY: Objection to</p> <p>9 form.</p> <p>10 THE WITNESS: There may have</p> <p>11 been a phone call. I don't</p> <p>12 recall.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Do you know who Ridge Hall</p> <p>15 is?</p> <p>16 A. Yes.</p> <p>17 Q. Who is he?</p> <p>18 A. He is with Crowell &amp; Moring,</p> <p>19 he is an attorney.</p> <p>20 Q. Right. And you met with --</p> <p>21 you met with -- you spoke with him, met</p> <p>22 with him, communicated with him over the</p> <p>23 years, correct?</p> <p>24 MR. HEGARTY: Objection to</p>

21 (Pages 78 to 81)



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<p style="text-align: right;">Page 82</p> <p>1 form.</p> <p>2 THE WITNESS: No.</p> <p>3 BY MR. TISI:</p> <p>4 Q. On talc-related issues? No?</p> <p>5 A. No.</p> <p>6 Q. Do you know how many</p> <p>7 documents on your privilege log relate to</p> <p>8 Mr. Hall?</p> <p>9 A. No.</p> <p>10 Q. All right. Doctor, let's</p> <p>11 get started here, and talk about some of</p> <p>12 the issues I'd like to discuss with you</p> <p>13 over the rest of the day today.</p> <p>14 I've put together -- just so</p> <p>15 you understand where I'm going to be</p> <p>16 going. Okay. And actually, I'm going to</p> <p>17 spend some time with you on four</p> <p>18 different areas. Okay.</p> <p>19 The first one I'm going to</p> <p>20 talk to you about your publications on</p> <p>21 talc. Okay. And you can look at it</p> <p>22 right up there.</p> <p>23 And the timelines of those</p> <p>24 publications. And your relationship with</p>	<p style="text-align: right;">Page 84</p> <p>1 answered.</p> <p>2 THE WITNESS: My published</p> <p>3 articles, yes.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay. Okay. I'm going to</p> <p>6 spend a brief amount of time talking</p> <p>7 about scientific principles that you have</p> <p>8 actually written, to see if we can agree</p> <p>9 on them. Okay?</p> <p>10 MR. HEGARTY: Objection to</p> <p>11 form.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Okay?</p> <p>14 A. Yes.</p> <p>15 Q. And then I want to talk</p> <p>16 about the reliability of the data and the</p> <p>17 methods used in your literature.</p> <p>18 A. Okay.</p> <p>19 Q. Okay. On talcum powder</p> <p>20 products and ovarian cancer. And that</p> <p>21 last part I'm going to talk to you about</p> <p>22 very specific pieces of data and -- and</p> <p>23 your methods. Okay?</p> <p>24 A. Okay.</p>
<p style="text-align: right;">Page 83</p> <p>1 the defendants, correct?</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay?</p> <p>6 A. Okay.</p> <p>7 Q. The second, I'm going to</p> <p>8 talk to you about talc industry funding</p> <p>9 of Muscat studies and regulatory reports.</p> <p>10 A. Okay.</p> <p>11 MR. HEGARTY: Objection to</p> <p>12 form.</p> <p>13 BY MR. TISI:</p> <p>14 Q. And you've just testified</p> <p>15 before, and I want to make absolutely</p> <p>16 clear, that it is your view that not a</p> <p>17 single one of your published articles was</p> <p>18 paid for directly or indirectly by any of</p> <p>19 the defendants in this case?</p> <p>20 MR. HEGARTY: Objection to</p> <p>21 form.</p> <p>22 MR. HUDSON: Objection to</p> <p>23 form.</p> <p>24 MR. HEGARTY: Asked and</p>	<p style="text-align: right;">Page 85</p> <p>1 Q. All right?</p> <p>2 A. Yes, mm-hmm.</p> <p>3 Q. And let me ask you this. In</p> <p>4 any article that you've ever written,</p> <p>5 when you sign your name to an article,</p> <p>6 you make sure that the information that</p> <p>7 is in that article is correct, accurate,</p> <p>8 and reflects your understanding of what</p> <p>9 the data means, correct?</p> <p>10 MR. HEGARTY: Objection to</p> <p>11 form.</p> <p>12 THE WITNESS: So, when I</p> <p>13 sign an article, I sign it for the</p> <p>14 purposes of -- I sign off on it,</p> <p>15 that's correct, so...</p> <p>16 BY MR. TISI:</p> <p>17 Q. Okay. I didn't -- I don't</p> <p>18 even know what that means.</p> <p>19 My question is, when you</p> <p>20 sign your name to an article, do you, in</p> <p>21 effect, certify to the scientific and</p> <p>22 medical community to the accuracy,</p> <p>23 integrity of the data, and the opinions</p> <p>24 and conclusions expressed in those</p>



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<p style="text-align: right;">Page 86</p> <p>1 articles?</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 MR. HUDSON: Objection to</p> <p>5 form.</p> <p>6 THE WITNESS: Okay. So</p> <p>7 it -- it depends a little bit on</p> <p>8 where you are in the article. So</p> <p>9 when I sign the article I'm</p> <p>10 signing my name to it, that to the</p> <p>11 best of my knowledge, that the</p> <p>12 data is accurate.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Okay. And the data and the</p> <p>15 conclusions and the methods are -- are</p> <p>16 yours, correct?</p> <p>17 A. If I'm the first author.</p> <p>18 Q. Okay. But even if you're</p> <p>19 second, third or last author, you are</p> <p>20 signing on to the integrity of that</p> <p>21 article, correct?</p> <p>22 A. That's correct.</p> <p>23 Q. Okay. And when you list the</p> <p>24 authors on the front of an article, you</p>	<p style="text-align: right;">Page 88</p> <p>1 the paper is an author.</p> <p>2 BY MR. TISI:</p> <p>3 Q. In fact, when you sign --</p> <p>4 you have to actually, when you submit an</p> <p>5 article for peer review, you have to</p> <p>6 actually sign and verify to the</p> <p>7 publication that the work is, A, yours,</p> <p>8 correct?</p> <p>9 Yes?</p> <p>10 A. That's correct, yes.</p> <p>11 Q. You have to identify anybody</p> <p>12 else who may have contributed</p> <p>13 substantively to the -- to the article,</p> <p>14 correct?</p> <p>15 A. That's correct.</p> <p>16 Q. You have to identify the</p> <p>17 source of funding, correct?</p> <p>18 A. That's correct.</p> <p>19 Q. You have to identify any</p> <p>20 potential conflicts of interest, correct?</p> <p>21 A. Yes.</p> <p>22 Q. Because all of those things</p> <p>23 can impact on whether or not a journal</p> <p>24 even publishes the article in the first</p>
<p style="text-align: right;">Page 87</p> <p>1 list the people who had primary</p> <p>2 responsibility for the research of that</p> <p>3 article, and the writing of that article,</p> <p>4 correct?</p> <p>5 MR. HEGARTY: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: The -- I mean,</p> <p>8 people have different roles in the</p> <p>9 production of the article. So it</p> <p>10 could either be the writing or the</p> <p>11 data analysis or the obtaining of</p> <p>12 the funding. So there's</p> <p>13 different -- different roles that</p> <p>14 different authors play.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Right. But the authors, all</p> <p>17 the people who had substantive</p> <p>18 involvement in the article are supposed</p> <p>19 to be listed in the byline of the article</p> <p>20 as authors, correct?</p> <p>21 MR. HUDSON: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: Anyone who</p> <p>24 makes a meaningful contribution to</p>	<p style="text-align: right;">Page 89</p> <p>1 place, correct?</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 THE WITNESS: Yes.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Okay. And it also impacts</p> <p>7 on anybody, if the article is published,</p> <p>8 the credibility in which the reader could</p> <p>9 attribute to the article, correct?</p> <p>10 MR. HUDSON: Objection to</p> <p>11 form.</p> <p>12 THE WITNESS: I'm sorry, can</p> <p>13 you repeat that?</p> <p>14 BY MR. TISI:</p> <p>15 Q. Yes. It also impacts on the</p> <p>16 disclosure of funding sources, of</p> <p>17 conflicts of interest, of who the authors</p> <p>18 are, are meaningful to the medical and</p> <p>19 scientific community that actually read</p> <p>20 your published work, correct?</p> <p>21 MR. HEGARTY: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: Yes.</p> <p>24 BY MR. TISI:</p>



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<p style="text-align: right;">Page 90</p> <p>1 Q. Now, going through these 2 four topics, I'd like to turn to Topic 3 Number 1, and that would be publications 4 and timelines. Okay. And we're going to 5 come back to this slide periodically, so 6 everyone who is reading this deposition 7 or looking at it, can understand where we 8 are. 9 A. Okay. 10 Q. Okay. All right. Now I put 11 together a slide here. I'm going to give 12 you a copy of this. But I put together a 13 list. I'm going to give you this. And 14 I'll mark it -- I'll give you this as 15 well. But you can -- Dr. Muscat. 16 I believe the other slide, 17 with all the articles and reports there 18 was one exception we're going to discuss, 19 and that's Number 4: Articles in which 20 you are listed as an author or co-author. 21 Do you -- first of all, do 22 you recognize these -- now, some are 23 articles -- 24 MR. LOCKE: Excuse me,</p>	<p style="text-align: right;">Page 92</p> <p>1 the binder contains the chart that I just 2 had, okay. And all of the documents that 3 are referred to in them. 4 A. Okay. 5 Q. In the back. To make our 6 lives easier. We may mark separately 7 some of these documents. But I want you 8 to have them, so it can make yours and my 9 life a little bit easier. 10 A. Okay. 11 Q. Okay. Now, the first 12 article, the first three articles, the 13 1997 article is a letter to the editor, 14 correct? 15 A. That's correct. 16 Q. Okay. And that's an article 17 you wrote in connection with your work at 18 the American Health Foundation, correct? 19 MR. HEGARTY: Objection to 20 form. 21 THE WITNESS: That's 22 correct. 23 BY MR. TISI: 24 Q. Okay. And that was written</p>
<p style="text-align: right;">Page 91</p> <p>1 Chris, can you just get that 2 clearer? 3 MR. TISI: Sure. Can you 4 fix it please? 5 MR. LOCKE: Thank you. 6 MR. TISI: You're welcome. 7 BY MR. TISI: 8 Q. Now, other than Number 4, 9 which we'll talk about in a moment, these 10 are articles and reports that have -- 11 bear your name, correct? 12 A. Yes. 13 Q. You recognize all of these? 14 A. Yes. 15 Q. And for reference I have 16 pulled together a notebook that I'd like 17 to have marked as the next exhibit. 18 (Document marked for 19 identification as Exhibit 20 Muscat-5.) 21 BY MR. TISI: 22 Q. I'm going to make this 23 Exhibit Number 5. 24 And just so, for the record,</p>	<p style="text-align: right;">Page 93</p> <p>1 in 1997? 2 A. Yes. 3 Q. And in 1998 you wrote a book 4 chapter on the epidemiology of talc 5 exposure and ovarian cancer, correct? 6 A. It wasn't for books. It was 7 a journal, special issue of a journal. 8 Q. Okay. And in 2000 you wrote 9 a -- that's the report to the National 10 Toxicology Project that we mentioned 11 before? 12 A. That's correct. 13 Q. The one that you wrote for 14 The Weinberg Group? 15 A. That's correct. 16 Q. Okay. These three are not 17 original research, are they, the first 18 three? 19 MR. HUDSON: Objection to 20 form. 21 BY MR. TISI: 22 Q. They are basically opinion 23 pieces, letters to the editor, 24 commentary, review articles?</p>



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<p style="text-align: right;">Page 94</p> <p>1 MR. SILVER: Objection.  2 BY MR. TISI:  3 Q. Correct?  4 Doctor, I'm going to  5 recommend --  6 A. I'm sorry, I want to clarify  7 something.  8 Q. Well, what are you looking  9 for? I may be able to help you.  10 A. The NTP submission.  11 Q. The NTP submission is  12 Number 3.  13 A. Yes, okay. So that's --  14 that's a meta-analysis that I did. I  15 would say that's original.  16 Q. Okay.  17 A. Okay. But the rest is  18 review.  19 Q. Okay. Did you actually do a  20 meta-analysis in connection with the NTP  21 review?  22 A. Yes.  23 Q. You actually did, you  24 actually did the data crunching?</p>	<p style="text-align: right;">Page 96</p> <p>1 A. Mm-hmm.  2 Q. Do you remember that? The  3 NTP ultimately deferred the question  4 about whether talc is a likely cause of  5 ovarian cancer, correct?  6 MR. HEGARTY: Objection to  7 form.  8 THE WITNESS: That's  9 correct.  10 BY MR. TISI:  11 Q. If anyone were to walk into  12 court and stand up and tell the judge and  13 the jury that the NTP rejected the  14 conclusion that talc causes ovarian  15 cancer, that would be incorrect, true?  16 MR. HUDSON: Objection to  17 form.  18 BY MR. TISI:  19 Q. They deferred the question?  20 MR. SILVER: Objection to  21 form.  22 THE WITNESS: That's all I  23 know is deferred.  24 BY MR. TISI:</p>
<p style="text-align: right;">Page 95</p> <p>1 A. I did it by hand, yes.  2 Q. You did it by hand.  3 Did Dr. Huncharek help you  4 with it?  5 A. No.  6 Q. No? Okay. We're going to  7 talk about that.  8 Let's go to the next section  9 which I put in red. And those are  10 articles in which a group called the  11 Meta-Analysis Research Group or MRG had  12 involvement, correct?  13 A. Yes.  14 Q. And you know what the  15 Meta-Analysis Research Group is, correct?  16 A. Yes, I do.  17 Q. What is the Meta-Analysis  18 Research Group?  19 A. That is a, I guess you would  20 call a consulting group that was  21 established by Dr. Huncharek.  22 Q. Now, before that -- actually  23 let me just ask one question. We talked  24 about the NTP process, the NTP review?</p>	<p style="text-align: right;">Page 97</p> <p>1 Q. Okay. Now, going back to  2 the American Health Foundation. In this  3 first time frame, in the 1990s, leading  4 up to the filing of the 2000 NTP report,  5 the American Health Foundation had been  6 under a consulting agreement with J&amp;J on  7 issues related to talc and ovarian  8 cancer, true?  9 MR. HEGARTY: Objection to  10 form.  11 MR. HUDSON: Objection to  12 form.  13 THE WITNESS: I'm not  14 familiar with that.  15 BY MR. TISI:  16 Q. You don't know whether or  17 not Dr. Wynder had signed a consulting  18 agreement with Johnson &amp; Johnson?  19 MR. HUDSON: Objection to  20 form.  21 THE WITNESS: No.  22 BY MR. TISI:  23 Q. You've actually met with,  24 during that time frame, in the 1990s, you</p>

25 (Pages 94 to 97)



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<p style="text-align: right;">Page 98</p> <p>1 actually met with Johnson &amp; Johnson</p> <p>2 people on talc-related issues, correct?</p> <p>3 A. That's correct.</p> <p>4 Q. Okay. In fact, you --</p> <p>5 actually, we'll talk about that. You</p> <p>6 actually drafted a proposed study on that</p> <p>7 issue, correct?</p> <p>8 A. That's correct.</p> <p>9 Q. A case-controlled study,</p> <p>10 correct?</p> <p>11 A. That's correct.</p> <p>12 Q. A \$400,000 study on the</p> <p>13 issue that had been discussed in the</p> <p>14 medical community for decades before,</p> <p>15 correct?</p> <p>16 MR. HEGARTY: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: I don't know</p> <p>19 how -- whether it was discussed</p> <p>20 for decades. But we did draft a</p> <p>21 proposal.</p> <p>22 BY MR. TISI:</p> <p>23 Q. They never funded it, did</p> <p>24 they?</p>	<p style="text-align: right;">Page 100</p> <p>1 they informed anybody --</p> <p>2 A. Okay.</p> <p>3 Q. -- about that.</p> <p>4 MR. HEGARTY: Objection to</p> <p>5 form.</p> <p>6 MR. HUDSON: Objection to</p> <p>7 form.</p> <p>8 BY MR. TISI:</p> <p>9 Q. But as far as you know, they</p> <p>10 kind of, throughout the 1990s, they kind</p> <p>11 of kept the issue of whether they would</p> <p>12 fund that study out there, and it was</p> <p>13 just something you never got an answer</p> <p>14 to, correct?</p> <p>15 MR. HUDSON: Objection to</p> <p>16 form, asked and answered.</p> <p>17 THE WITNESS: I don't</p> <p>18 remember an exact date.</p> <p>19 There was obviously a point</p> <p>20 where we knew it was not going to</p> <p>21 be funded so...</p> <p>22 BY MR. TISI:</p> <p>23 Q. But you continued to speak</p> <p>24 with folks at J&amp;J on talc-related issues,</p>
<p style="text-align: right;">Page 99</p> <p>1 A. No.</p> <p>2 Q. They never actually gave you</p> <p>3 a formal answer, did they?</p> <p>4 MR. SILVER: Objection to</p> <p>5 form.</p> <p>6 BY MR. TISI:</p> <p>7 Q. To whether or not they would</p> <p>8 fund it?</p> <p>9 A. I never received a formal</p> <p>10 answer.</p> <p>11 Q. You just kind of left it</p> <p>12 kind of hanging out there, right?</p> <p>13 MR. HUDSON: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: It was -- I</p> <p>16 mean I'm sure that information was</p> <p>17 transmitted to the American Health</p> <p>18 Foundation but not to me</p> <p>19 personally.</p> <p>20 BY MR. TISI:</p> <p>21 Q. Okay. Well, we looked all</p> <p>22 over the document. We couldn't see any</p> <p>23 place where they denied funding, that</p> <p>24 they decided that they weren't -- that</p>	<p style="text-align: right;">Page 101</p> <p>1 correct?</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 BY MR. TISI:</p> <p>5 Q. In the -- in the 1990s?</p> <p>6 A. I don't have any specific</p> <p>7 recollection.</p> <p>8 Q. Do you know John Hopkins?</p> <p>9 A. Yes.</p> <p>10 Q. You met with him, correct?</p> <p>11 A. He was at the meeting in</p> <p>12 Skillman, New Jersey.</p> <p>13 Q. And you communicated back</p> <p>14 and forth, letters with him in the 1990s</p> <p>15 on issues related to epidemiology and</p> <p>16 talc?</p> <p>17 MR. HEGARTY: Objection to</p> <p>18 form.</p> <p>19 THE WITNESS: I don't recall</p> <p>20 specifically.</p> <p>21 BY MR. TISI:</p> <p>22 Q. You don't remember him</p> <p>23 e-mailing -- talk -- sending you letters</p> <p>24 and you going back and forth about the</p>



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<p style="text-align: right;">Page 102</p> <p>1 Cook study?</p> <p>2 MR. HEGARTY: Objection.</p> <p>3 THE WITNESS: I can't</p> <p>4 remember that. I'd have to see</p> <p>5 that.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Okay. Well, we'll show you</p> <p>8 that in a moment.</p> <p>9 A. Okay.</p> <p>10 Q. Do you know who Don Jones</p> <p>11 is?</p> <p>12 A. Yes.</p> <p>13 Q. Who is Don Jones?</p> <p>14 A. He was an executive at</p> <p>15 Johnson &amp; Johnson.</p> <p>16 Q. You met with him, true?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. Do you know who John</p> <p>19 O'Shaughnessy is?</p> <p>20 A. I'm sorry, who?</p> <p>21 Q. John O'Shaughnessy.</p> <p>22 A. No.</p> <p>23 Q. Have you ever met with any</p> <p>24 lawyers at J&amp;J in the 1990s, to your</p>	<p style="text-align: right;">Page 104</p> <p>1 not the funding, their research was</p> <p>2 compromised because of their funding from</p> <p>3 Phillip Morris.</p> <p>4 Do you remember hearing</p> <p>5 that?</p> <p>6 MR. HUDSON: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: No.</p> <p>9 BY MR. TISI:</p> <p>10 Q. You never heard that?</p> <p>11 A. No.</p> <p>12 Q. Never heard that at all?</p> <p>13 MR. HUDSON: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: No, never.</p> <p>16 BY MR. TISI:</p> <p>17 Q. Okay. Let's go back to the</p> <p>18 list of publications here. The second</p> <p>19 group of papers, 4 through 9, are ones</p> <p>20 that you recognized. And we talked</p> <p>21 about, those were the ones that were</p> <p>22 associated with Dr. Huncharek's company</p> <p>23 called Meta-Analysis Research Group?</p> <p>24 A. That's correct.</p>
<p style="text-align: right;">Page 103</p> <p>1 knowledge?</p> <p>2 A. No.</p> <p>3 Q. Now, at some point did</p> <p>4 American Health Foundation go out of</p> <p>5 business?</p> <p>6 A. Yes.</p> <p>7 Q. In fact, it went out of</p> <p>8 business under -- under some questionable</p> <p>9 circumstances, correct? There had been</p> <p>10 questions raised about the proprietary of</p> <p>11 the American Health Association and its</p> <p>12 funding by cigarette manufacturers,</p> <p>13 correct?</p> <p>14 MR. HUDSON: Objection to</p> <p>15 form.</p> <p>16 THE WITNESS: So it ceased</p> <p>17 operations, had already changed</p> <p>18 its name. It was no longer called</p> <p>19 the American Health Foundation.</p> <p>20 It was called the Institute For</p> <p>21 Cancer Prevention.</p> <p>22 BY MR. TISI:</p> <p>23 Q. Right. But it was -- there</p> <p>24 were some real questions about whether or</p>	<p style="text-align: right;">Page 105</p> <p>1 Q. And it's also called MRG?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. MRG is not in</p> <p>4 business anymore, is it?</p> <p>5 A. I don't know actually. I</p> <p>6 don't know.</p> <p>7 Q. It kind of went out of</p> <p>8 business to your knowledge?</p> <p>9 MR. HUDSON: Objection to</p> <p>10 form.</p> <p>11 THE WITNESS: You'd have to</p> <p>12 ask him. I don't know.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Have you ever asked him?</p> <p>15 A. No.</p> <p>16 Q. When you spoke to him a</p> <p>17 couple months ago, did you tell him that</p> <p>18 you were involved in the talc litigation?</p> <p>19 A. Yes, I did.</p> <p>20 Q. Okay. Did you ask him</p> <p>21 whether he had any documents related to</p> <p>22 the talc litigation?</p> <p>23 A. No.</p> <p>24 Q. Did you ask him whether he</p>



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<p style="text-align: right;">Page 106</p> <p>1 was going to be involved in the talc 2 litigation? 3 A. He had mentioned that he had 4 gotten a subpoena. 5 Q. Did he in any way -- did you 6 and he talk about the subpoena? 7 A. No. 8 Q. Did you talk about any 9 documents that would be collected? 10 A. No. 11 Q. You had a Meta-Analysis 12 Research Group e-mail account, did you 13 not? 14 A. No. 15 Q. Okay. Where did you get 16 e-mails related to your work for 17 Meta-Analysis Research Group? 18 A. I'm sorry, can you ask the 19 question again? 20 I -- I wasn't -- in terms of 21 the work at the Meta-Analysis Research 22 Group, I was on a list of consultants. 23 All the projects were generated by 24 Dr. Huncharek.</p>	<p style="text-align: right;">Page 108</p> <p>1 form. 2 MR. HEGARTY: Objection. 3 THE WITNESS: So my name was 4 listed on papers under that 5 affiliation, that's correct. 6 BY MR. TISI: 7 Q. Okay. Now, Meta-Analysis 8 Research Group was a for-profit group 9 that hired itself out to pharmaceutical 10 companies to do research, correct? 11 MR. HEGARTY: Objection to 12 form. 13 THE WITNESS: Not to my 14 knowledge. 15 BY MR. TISI: 16 Q. Not to your knowledge. 17 A. Yeah. 18 Q. Do you know what their -- 19 did you ever bother -- you were 20 affiliated with them for years. Did you 21 ever bother to ask them what their 22 affiliations were, what the scope of 23 their work was? 24 A. The only thing that I knew</p>
<p style="text-align: right;">Page 107</p> <p>1 Q. But you were listed as a 2 senior scientist? 3 A. That's correct. 4 Q. Okay. And you actually 5 signed your name for example, to the 6 Citizen's Petition in your academic 7 capacity but also as a consultant for 8 Meta-Analysis Research Group, for 9 example? 10 A. Yes. My name was on that. 11 Q. Right. For Meta-Analysis 12 Research Group? 13 A. Yes. 14 Q. And in the published 15 articles, when they drop the little 16 footnotes that say what your affiliations 17 are, it listed you as Meta-Analysis 18 Research Group. 19 A. Yes. 20 Q. Okay. So when you were 21 writing articles, you were writing 22 articles for Meta-Analysis Research 23 Group, correct? 24 MR. HUDSON: Objection to</p>	<p style="text-align: right;">Page 109</p> <p>1 is actually it was not a for-profit 2 institution. 3 Q. Did you -- I mean you've 4 known Dr. Huncharek, I saw your CV, 5 you've known him for years, right? 6 A. That's correct. 7 Q. Okay. You published him 8 before Meta-Analysis Research Group, 9 correct? 10 A. That's correct. 11 Q. You haven't published with 12 him recently, have you? 13 A. No. 14 Q. Any reason why? 15 A. I'm very busy at work and -- 16 Q. Has he asked you to be on 17 any publications recently, you know, in 18 the past ten years? 19 A. No, not to my knowledge. 20 Q. Have you talked about doing 21 any further work with him on talc? 22 A. No. 23 Q. I'm going to show you a 24 document which I'd like to have marked as</p>



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<p style="text-align: right;">Page 110</p> <p>1 Exhibit Number 6. 2 (Document marked for 3 identification as Exhibit 4 Muscat-6.) 5 BY MR. TISI: 6 Q. Now, I'm actually not going 7 to ask you too much about the front pages 8 here. 9 A. Okay. 10 Q. But -- but bear with me a 11 moment. 12 This is a document from 2004 13 from -- to Bob Glenn from Dr. Huncharek, 14 correct? 15 Do you see that? 16 A. Yes. 17 Q. And Mr. Glenn, as you know, 18 was the toxicologist consultant for the 19 law firm of Crowell &amp; Moring? 20 A. Yes. 21 Q. And this is an agreement, 22 attached to it is an agreement proposal 23 for talc projects, do you see that? 24 MR. HEGARTY: Objection to</p>	<p style="text-align: right;">Page 112</p> <p>1 sentence says, "MRG participating" -- "at 2 MRG, practicing scientists and clinicians 3 with substantial research and business 4 experience join together to produce 5 quantitative synthesis of clinical data 6 of the highest quality," correct? 7 A. I'm sorry, which paragraph 8 is that? 9 Q. Last -- first paragraph, 10 last sentence. 11 A. Okay. Okay. Yes. 12 Q. So he emphasized both 13 research and business experience, do you 14 see that? 15 A. Yes. 16 Q. Okay. It goes on to say in 17 the last paragraph, it says, "We have 18 assisted major pharmaceutical 19 companies" -- "pharmaceutical, 20 Schering-Plough, Bayer, Warner Lambert 21 and other clients in deciphering often 22 complex, seemingly contradictory data 23 using rigorous meta-analytical methods." 24 Do you see that?</p>
<p style="text-align: right;">Page 111</p> <p>1 form. 2 BY MR. TISI: 3 Q. I'm not going to ask you -- 4 A. Okay. Okay. 5 Q. You see the agreement? 6 A. Right, right. Yeah, right. 7 Q. Go to the next two pages in, 8 three pages in, and it is an 9 informational brochure for the 10 Meta-Analysis Research Group. Do you see 11 that? Right there. 12 A. Yes. 13 Q. Okay. And it's information 14 about the organization. Do you see that? 15 A. Yes, I see that. 16 Q. If you look, it said it was 17 formed in 1996 by Dr. Huncharek, correct? 18 A. Yes. 19 Q. Okay. Do you know that 20 Dr. Huncharek was working with the 21 Meta-Analysis Research Group from about 22 that time? 23 A. Sounds reasonable. 24 Q. Then it goes on, the last</p>	<p style="text-align: right;">Page 113</p> <p>1 A. Mm-hmm. Yes. 2 Q. And deciphering is in 3 quotations, right? 4 A. Yes. 5 Q. Okay. And so you 6 understand, and understood at the time, 7 that a lot of their clients of 8 Meta-Analysis Research Group were 9 pharmaceutical companies, correct? 10 MR. HUDSON: Objection to 11 form. 12 THE WITNESS: I'm sorry, can 13 you repeat the question? 14 BY MR. TISI: 15 Q. Did you understand at the 16 time that Meta-Analysis Research Group 17 had worked for pharmaceutical companies? 18 MR. HUDSON: Objection to 19 form. 20 BY MR. TISI: 21 Q. As is listed here? 22 A. Yes. So I don't even recall 23 seeing this. 24 Q. Okay. But I'm asking you --</p>



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<p style="text-align: right;">Page 114</p> <p>1 I'm using this as the guideline --</p> <p>2 A. Okay.</p> <p>3 Q. -- to see whether or not</p> <p>4 this helps you recall what Meta-Analysis</p> <p>5 Research Group is, and what it did.</p> <p>6 A. Okay.</p> <p>7 Q. Okay?</p> <p>8 Did it work for</p> <p>9 pharmaceutical companies as listed here,</p> <p>10 to your knowledge?</p> <p>11 MR. HUDSON: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: That's what it</p> <p>14 says. We have assisted major</p> <p>15 pharmaceutical and other clients,</p> <p>16 that's correct.</p> <p>17 BY MR. TISI:</p> <p>18 Q. And in the context of your</p> <p>19 work with -- with Meta-Analysis Research</p> <p>20 Group, you were writing papers in</p> <p>21 connection with contracts with the</p> <p>22 defendants in this case, correct?</p> <p>23 MR. HEGARTY: Objection to</p> <p>24 form.</p>	<p style="text-align: right;">Page 116</p> <p>1 A. Yes.</p> <p>2 Q. Okay. You are unaware of a</p> <p>3 contract in which you were -- were tasked</p> <p>4 with writing papers that were funded by</p> <p>5 the defendant that were ultimately</p> <p>6 published?</p> <p>7 MR. HUDSON: Objection to</p> <p>8 form, asked and answered.</p> <p>9 THE WITNESS: There was work</p> <p>10 that was done with the</p> <p>11 Meta-Analysis Research Group,</p> <p>12 that's correct.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Okay. And that work was</p> <p>15 funded by the defendants in this case,</p> <p>16 correct?</p> <p>17 MR. HUDSON: Objection to</p> <p>18 form.</p> <p>19 BY MR. TISI:</p> <p>20 Q. J&amp;J and Imerys?</p> <p>21 MR. HEGARTY: Same</p> <p>22 objection.</p> <p>23 MR. HUDSON: Objection.</p> <p>24 THE WITNESS: There was a --</p>
<p style="text-align: right;">Page 115</p> <p>1 THE WITNESS: I'm sorry, can</p> <p>2 you repeat the question?</p> <p>3 BY MR. TISI:</p> <p>4 Q. Yes.</p> <p>5 A. Yeah.</p> <p>6 Q. In connection with your</p> <p>7 affiliation with Meta-Analysis Research</p> <p>8 Group, you were writing articles for</p> <p>9 the -- in the medical literature, that</p> <p>10 were funded in whole or in part by the</p> <p>11 defendants in this case?</p> <p>12 MR. HUDSON: Objection to</p> <p>13 form.</p> <p>14 MR. SILVER: Asked and</p> <p>15 answered.</p> <p>16 BY MR. TISI:</p> <p>17 Q. Or -- individually or</p> <p>18 collectively?</p> <p>19 A. No.</p> <p>20 Q. No?</p> <p>21 A. No.</p> <p>22 Q. You don't think -- I mean</p> <p>23 I've asked you this three times already.</p> <p>24 I'm going to ask you one more time.</p>	<p style="text-align: right;">Page 117</p> <p>1 a meta-analysis talking about the</p> <p>2 diaphragms, right? Is that what</p> <p>3 you're referring to?</p> <p>4 BY MR. TISI:</p> <p>5 Q. I'm asking you the</p> <p>6 questions, Doctor. You tell me. I'm not</p> <p>7 trying to drag you around by your nose</p> <p>8 here. Okay.</p> <p>9 I'm asking you, were there</p> <p>10 papers that were written on this list</p> <p>11 that we have --</p> <p>12 A. I can't speak for all of the</p> <p>13 clients of the Meta-Analysis Research</p> <p>14 Group and what was published. I -- I</p> <p>15 wasn't -- it wasn't my group. I don't</p> <p>16 know what you expect from me. So all</p> <p>17 these things -- Plough, Schering, I -- I</p> <p>18 have no knowledge of it.</p> <p>19 Q. Well, was it important to</p> <p>20 you to know where your funding came from?</p> <p>21 A. Yeah, I know where my</p> <p>22 funding comes from. Right.</p> <p>23 Q. You know that for these</p> <p>24 articles, for some of these articles,</p>



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<p>1 your funding to write these articles came</p> <p>2 from defendants, correct?</p> <p>3 MR. SILVER: Objection to</p> <p>4 form. Asked and answered.</p> <p>5 MR. HUDSON: Objection to</p> <p>6 form. Asked and answered.</p> <p>7 THE WITNESS: So -- yes.</p> <p>8 Okay.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Let's take one for example.</p> <p>11 2007, the critical -- I'm sorry. 2008,</p> <p>12 The Critical Review, Perineal Talc and</p> <p>13 Ovarian Cancer that was published in the</p> <p>14 European Journal of Cancer Prevention.</p> <p>15 A. Yes.</p> <p>16 Q. That article was actually</p> <p>17 written in connection with the contract</p> <p>18 with members of the talc industry,</p> <p>19 correct?</p> <p>20 MR. HUDSON: Objection to</p> <p>21 form.</p> <p>22 BY MR. TISI:</p> <p>23 Q. Including Johnson &amp; Johnson</p> <p>24 and Imerys?</p>	<p>1 form.</p> <p>2 THE WITNESS: No.</p> <p>3 BY MR. TISI:</p> <p>4 Q. No?</p> <p>5 A. No.</p> <p>6 Q. Now, another thing the</p> <p>7 Meta-Analysis Research Group says it does</p> <p>8 is medical/legal consulting. If you go</p> <p>9 to the next page.</p> <p>10 Page 4.6. Do you see that?</p> <p>11 It says medical and legal consulting.</p> <p>12 A. Yes.</p> <p>13 Q. Did you know that the</p> <p>14 Meta-Analysis Research Group did medical</p> <p>15 and legal consulting?</p> <p>16 A. I don't know what they did.</p> <p>17 I wasn't --</p> <p>18 Q. I didn't ask you that.</p> <p>19 A. -- actively following what</p> <p>20 the Meta-Analysis Research Group did.</p> <p>21 Q. I asked you, did you know</p> <p>22 that, that they did that at the time?</p> <p>23 A. Did I know that they did</p> <p>24 medical and legal -- I'm unaware of any</p>
Page 119	Page 121
<p>1 MR. HUDSON: Objection.</p> <p>2 THE WITNESS: No.</p> <p>3 BY MR. TISI:</p> <p>4 Q. It was not?</p> <p>5 A. It was not.</p> <p>6 Q. Okay. That had -- that</p> <p>7 article had absolutely nothing to do</p> <p>8 with -- with the contract that you</p> <p>9 entered into with the -- with the</p> <p>10 company?</p> <p>11 MR. HEGARTY: Objection to</p> <p>12 form.</p> <p>13 MR. HUDSON: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: It -- that</p> <p>16 article was independent of the</p> <p>17 work that was done for the</p> <p>18 company.</p> <p>19 BY MR. TISI:</p> <p>20 Q. You drafted that paper and</p> <p>21 it was reviewed by Crowell &amp; Moring</p> <p>22 before it was published in the</p> <p>23 peer-reviewed literature, correct?</p> <p>24 MR. HEGARTY: Objection to</p>	<p>1 medical and legal consulting that they've</p> <p>2 done.</p> <p>3 Q. Did you ever get asked by</p> <p>4 Dr. Huncharek or his group to do medical</p> <p>5 and legal consulting for anybody?</p> <p>6 A. So I'm not a physician so I</p> <p>7 wouldn't be doing medical consulting.</p> <p>8 Q. Okay.</p> <p>9 A. Okay.</p> <p>10 Q. How about scientific</p> <p>11 consulting?</p> <p>12 A. It depends. Were you</p> <p>13 referring to something specifically?</p> <p>14 Q. I'm asking you, Doctor.</p> <p>15 A. Yes.</p> <p>16 Q. Had Meta-Analysis Research</p> <p>17 Group ever asked you to do any work as a</p> <p>18 consultant or expert in legal matters?</p> <p>19 A. In legal matters?</p> <p>20 Q. In -- yes. Legal</p> <p>21 consulting. Let's use that.</p> <p>22 A. Legal consulting, no.</p> <p>23 Q. No. Never?</p> <p>24 A. Legal consulting, no.</p>

31 (Pages 118 to 121)



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<p style="text-align: right;">Page 122</p> <p>1 Q. Now, all of the articles 2 here listed on this chart which I 3 provided in the front of the binder that 4 you said you recognized all of them. 5 Other than Number 4 which is 6 one we'll talk about in a moment, is -- 7 were written or co-written by you or the 8 Meta-Analysis Research Group, correct? 9 A. That's correct. 10 Q. And item Number 4, let's 11 talk about that for a moment. We're 12 going to come back to that one. 13 That is entitled Perineal 14 Application of Cosmetic Talc As a Risk 15 Factor For Ovarian Cancer: A 16 meta-analysis of 11,229 subjects from 16 17 observational studies, published in the 18 Anti-Cancer Research Journal, correct? 19 A. Yes. 20 Q. Okay. The Anti-Cancer 21 Research Journal is -- is a foreign 22 journal, correct? 23 You have published in it 24 yourself.</p>	<p style="text-align: right;">Page 124</p> <p>1 A. I can't recall specifically 2 if I had absolutely no idea. But I was 3 uninvolved in it. I was unaware of it. 4 Q. Okay. And you don't know 5 whether or not a research proposal was 6 submitted on this data in 2000 that -- 7 that included your name on it by 8 Dr. Huncharek? 9 A. To who? 10 Q. Johnson &amp; Johnson? 11 A. So I just became aware of 12 that within the last month. 13 Q. Okay. He -- so he put your 14 name, Dr. Huncharek put your name down, 15 does it refresh -- let me ask you this. 16 Does it refresh your 17 recollection as to whether or not you 18 were aware of this study proposal in 19 2000? 20 A. So I was not aware of it. 21 Q. So he put your name down 22 without ever having asked you? 23 A. That's my recollection, yes. 24 Q. Just kind of said, well, you</p>
<p style="text-align: right;">Page 123</p> <p>1 A. I probably have, yes. 2 Q. It's based in like Athens, 3 Greece, or something like that? 4 A. Yeah. Yeah, something like 5 that, yeah. 6 Q. It's not an American 7 journal, is it? 8 A. I think at the time, I think 9 it was based in Greece. 10 Q. You were aware of this study 11 before it was published, were you not? 12 A. No. 13 Q. You were not aware of it at 14 all? 15 A. No. 16 Q. You'd never been provided 17 with a -- you never were involved in the 18 design of the study or a proposal for -- 19 for what ultimately became this study? 20 A. That's correct. 21 Q. And when this study came on 22 the scene, you had absolutely no idea 23 that he had done a meta-analysis of 24 11,229 subjects?</p>	<p style="text-align: right;">Page 125</p> <p>1 know, I'm just going to put Dr. Muscat 2 down on this proposal to Johnson &amp; 3 Johnson? 4 MR. HUDSON: Objection to 5 form. 6 THE WITNESS: I was unaware 7 of it. 8 BY MR. TISI: 9 Q. Now, when you updated your 10 CV in July of '18, did you list your 11 affiliation with Meta-Analysis Research 12 Group? 13 A. No. 14 Q. Can you tell the members of 15 the jury why you never identified 16 yourself in your -- in your CV as having 17 been a senior scientist for Meta-Analysis 18 Research Group? 19 A. So usually what I keep now 20 is what's called an academic CV. And 21 there are certain things that are 22 expected to be on that. So academic CVs 23 are for purposes of submitting a -- your 24 credentials for let's say a grant</p>



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<p style="text-align: right;">Page 126</p> <p>1 application to NIH or some other 2 organization. So they look for certain 3 things. And there are certain things 4 that are expected and required on it. 5 So that's my -- my academic 6 CV fits those -- those requirements. It 7 doesn't mean -- they are not looking for 8 consulting work. 9 Q. What about your other CVs 10 that you said you might have kept for 11 other reasons? Do you -- 12 A. No one -- no one has really 13 asked me for -- that's the main reason I 14 keep my CV, my academic CV, I update it 15 almost weekly. I spend a lot of time 16 doing it. It's a lot of work. That's 17 about as much work I can do on CVs as 18 possible. 19 Q. It takes work to actually 20 omit things and take things off your CV, 21 true? 22 MR. HEGARTY: Objection to 23 form. 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 128</p> <p>1 other organizations that represented 2 pharmaceutical companies? 3 MR. HUDSON: Objection to 4 form. 5 THE WITNESS: I don't 6 know -- so, first of all, I don't 7 know if I took anything off. This 8 is something that I may -- it may 9 still be in there for all I know. 10 For all I know it's for -- 11 BY MR. TISI: 12 Q. It's not. 13 A. Okay. 14 Q. It's not in your current -- 15 in your CV that you produced to us in 16 2018. 17 A. Okay. 18 Q. Okay? 19 A. I may have other CVs, okay. 20 But I -- the CVs that I work on, that I 21 spend time on for probably the last at 22 least seven or eight years is my academic 23 CV. I do it to fit a specific required 24 format. I update it as -- as it is</p>
<p style="text-align: right;">Page 127</p> <p>1 Q. I mean, you took -- you took 2 consulting activities off of your CV, 3 correct? 4 A. Off the CV at that time, 5 that's correct. 6 Q. All right. And the things 7 you took off your CV was consulting 8 with -- with organizations and lawyers 9 who were working with pharmaceutical 10 companies, correct? 11 MR. HEGARTY: Objection to 12 form. 13 THE WITNESS: So, I'll just 14 repeat myself. The work that I do 15 for -- on my CV over the last few 16 years has been -- 17 BY MR. TISI: 18 Q. I'm not asking you that 19 question, Doctor? 20 A. Yes. 21 Q. Okay. My question is, you 22 took off of your CV, you physically took 23 off your earlier CV, consulting 24 activities you did with law firms and</p>	<p style="text-align: right;">Page 129</p> <p>1 needed. 2 Q. Okay. Let's -- 3 MR. HUDSON: Counsel, when 4 you get a break, can we take a 5 short morning break? I know we've 6 been going about an hour and a 7 half. Whenever you get to a 8 stopping point -- 9 MR. TISI: I don't know that 10 we've been running about an hour 11 and a half. But we'll just 12 definitely -- we can take a break. 13 MR. HUDSON: Okay. Thank 14 you. I appreciate it very much. 15 MR. TISI: Okay. 16 THE VIDEOGRAPHER: Going off 17 the record, 11:08 a.m. 18 (Short break.) 19 THE VIDEOGRAPHER: We are 20 back on the record, 11:21 a.m. 21 BY MR. TISI: 22 Q. Doctor, I want to talk about 23 Reference Number 4 for a moment which is 24 the Huncharek 2003 meta-analysis.</p>



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<p style="text-align: right;">Page 130</p> <p>1 A. Okay.</p> <p>2 Q. Okay. When I talk about</p> <p>3 that, you know what I'm talking about,</p> <p>4 the 2003 meta-analysis involving ovarian</p> <p>5 cancer and talc, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And in that article, we</p> <p>8 can -- we'll talk about it more later on.</p> <p>9 A. Okay.</p> <p>10 Q. But -- but the authors found</p> <p>11 overall meta-analysis across all studies,</p> <p>12 approximately 33 percent increased risk</p> <p>13 but a difference between individual study</p> <p>14 categories, correct?</p> <p>15 MR. HEGARTY: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: That's</p> <p>18 correct.</p> <p>19 BY MR. TISI:</p> <p>20 Q. All right. And</p> <p>21 Dr. Huncharek concluded that there was --</p> <p>22 there were reasons that argued against</p> <p>23 causation even in the presence of</p> <p>24 association, correct?</p>	<p style="text-align: right;">Page 132</p> <p>1 believe it's Number 6. That's your</p> <p>2 article on diaphragms, correct?</p> <p>3 MR. HEGARTY: Objection to</p> <p>4 form.</p> <p>5 THE WITNESS: 6 is the</p> <p>6 Huncharek meta-analysis.</p> <p>7 BY MR. TISI:</p> <p>8 Q. 6 is the -- I'm sorry.</p> <p>9 A. In my binder.</p> <p>10 Q. 6 is the Huncharek -- this</p> <p>11 is the diaphragm study.</p> <p>12 A. Oh, okay.</p> <p>13 Q. This is your -- your 2007</p> <p>14 diaphragm study.</p> <p>15 A. Okay.</p> <p>16 Q. And it's P2-002.</p> <p>17 A. I'm sorry. Okay. 4?</p> <p>18 Q. I'm sorry.</p> <p>19 A. That -- is that the</p> <p>20 meta-analysis you're referring to?</p> <p>21 Q. No. Let's start all over</p> <p>22 again, Doctor.</p> <p>23 A. Okay.</p> <p>24 Q. Number 6 in your binder is</p>
<p style="text-align: right;">Page 131</p> <p>1 MR. HEGARTY: Objection to</p> <p>2 form.</p> <p>3 THE WITNESS: So I -- I'd</p> <p>4 have to read -- you don't want me</p> <p>5 to read it or --</p> <p>6 BY MR. TISI:</p> <p>7 Q. I don't.</p> <p>8 A. Okay.</p> <p>9 Q. But you relied heavily --</p> <p>10 let me put it this way. You relied</p> <p>11 heavily in your published medical</p> <p>12 literature on this 2003 article, correct?</p> <p>13 MR. HUDSON: Objection to</p> <p>14 form.</p> <p>15 BY MR. TISI:</p> <p>16 Q. You cite it over and over</p> <p>17 and over again?</p> <p>18 A. It gets cited, that's</p> <p>19 correct.</p> <p>20 Q. But you cite it often.</p> <p>21 So for example, if you go to</p> <p>22 your tabbed binder. If you go to your</p> <p>23 article on diaphragms which is Number 4.</p> <p>24 I'm sorry, number -- I'm sorry. I</p>	<p style="text-align: right;">Page 133</p> <p>1 your 2003 study, the meta-analysis</p> <p>2 involving diaphragms.</p> <p>3 MR. HUDSON: Objection to</p> <p>4 form.</p> <p>5 THE WITNESS: The use of</p> <p>6 contraceptive talc and</p> <p>7 contraceptive diaphragms, that's</p> <p>8 correct.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Correct. And that's your</p> <p>11 study, correct?</p> <p>12 A. I'm a co-author on it.</p> <p>13 Q. And because you are on the</p> <p>14 byline as we talked about before, you --</p> <p>15 you agree to all the contents in this,</p> <p>16 and you wouldn't lend your name to</p> <p>17 something that had wrong information in</p> <p>18 it, correct?</p> <p>19 A. That's correct.</p> <p>20 Q. All right. So if you look</p> <p>21 at Page 425, there's a whole paragraph</p> <p>22 about in a prior meta-analysis, we</p> <p>23 demonstrated. Do you see that? On the</p> <p>24 right-hand column, on Page 425.</p>

34 (Pages 130 to 133)



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<p style="text-align: right;">Page 134</p> <p>1 A. Yes.</p> <p>2 Q. Okay. So you're relying on</p> <p>3 that -- that article here. And then you</p> <p>4 wrote -- go to the next tab. That's The</p> <p>5 Critical Review that you wrote with</p> <p>6 Dr. Huncharek, correct?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. And on Page 143,</p> <p>9 left-hand column, you talk about</p> <p>10 Huncharek et al. 2003, correct?</p> <p>11 A. Yes.</p> <p>12 Q. And on -- you go to Tab</p> <p>13 Number 8, which is the report you sent to</p> <p>14 the FDA. Go to Tab Number 8, sir. And</p> <p>15 that's 164. If you go to Page 4.</p> <p>16 This is your report to</p> <p>17 the -- this is your report -- go a couple</p> <p>18 pages in.</p> <p>19 A. Mm-hmm.</p> <p>20 Q. This attaches your report to</p> <p>21 the FDA by Dr. Huncharek and Dr. Muscat,</p> <p>22 correct?</p> <p>23 A. That's correct.</p> <p>24 Q. And if you go, there's a</p>	<p style="text-align: right;">Page 136</p> <p>1 A. The Table 3, yes.</p> <p>2 Q. And it actually came from</p> <p>3 Huncharek 2000 -- that came from</p> <p>4 Huncharek 2003, correct?</p> <p>5 A. I'd have to go back and</p> <p>6 look. I take your word for it.</p> <p>7 Q. Right. It says, "Table 3</p> <p>8 derived from data presented in the</p> <p>9 meta-analysis by Huncharek et al.</p> <p>10 displays dose-response data for those</p> <p>11 include studies provided that</p> <p>12 information."</p> <p>13 Do you see that?</p> <p>14 A. Okay.</p> <p>15 Q. Okay. And so it's fair to</p> <p>16 say throughout your published medical</p> <p>17 literature, you relied heavily, or let's</p> <p>18 say relied, on Huncharek 2003,</p> <p>19 particularly with -- with respect to the</p> <p>20 dose-response issue, correct?</p> <p>21 MR. HEGARTY: Objection to</p> <p>22 form.</p> <p>23 MR. HUDSON: Objection to</p> <p>24 form.</p>
<p style="text-align: right;">Page 135</p> <p>1 discussion in here about Muscat 2003,</p> <p>2 correct?</p> <p>3 MR. HEGARTY: Objection to</p> <p>4 form.</p> <p>5 MR. HUDSON: Objection to</p> <p>6 form.</p> <p>7 BY MR. TISI:</p> <p>8 Q. If you go to Page 23 -- 24,</p> <p>9 excuse me. Last paragraph. It says,</p> <p>10 Huncharek 2003 and Huncharek and Muscat</p> <p>11 2007. Do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. In fact, it refers to</p> <p>14 a specific -- it talks about the</p> <p>15 dose-response analysis done in the 2003</p> <p>16 meta-analysis by Huncharek?</p> <p>17 A. Okay.</p> <p>18 Q. Is that correct?</p> <p>19 And if you go to your final</p> <p>20 article which is a 2011 article,</p> <p>21 Number 9. You actually reproduce a</p> <p>22 chart, Table 3, that came from Huncharek</p> <p>23 2003, correct?</p> <p>24 Do you see that?</p>	<p style="text-align: right;">Page 137</p> <p>1 THE WITNESS: No.</p> <p>2 BY MR. TISI:</p> <p>3 Q. You didn't -- I mean we just</p> <p>4 looked in an article where you actually</p> <p>5 republished the table that was in the</p> <p>6 2003 article, correct?</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: Yeah. So I'm</p> <p>10 not sure what you mean, do I rely</p> <p>11 heavily for --</p> <p>12 BY MR. TISI:</p> <p>13 Q. I said did you rely on it.</p> <p>14 A. Yes, I relied it.</p> <p>15 Q. Okay.</p> <p>16 A. But you asked me if I relied</p> <p>17 heavily on it. So I'm not sure what that</p> <p>18 means. I didn't rely heavily on --</p> <p>19 heavily on these tables.</p> <p>20 Q. Okay.</p> <p>21 A. Okay.</p> <p>22 Q. That -- that table is</p> <p>23 inaccurate, isn't it?</p> <p>24 MR. HUDSON: Objection to</p>

35 (Pages 134 to 137)



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<p style="text-align: right;">Page 138</p> <p>1 form.</p> <p>2 THE WITNESS: I don't know</p> <p>3 what you mean.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay. We'll talk about</p> <p>6 that.</p> <p>7 A. Okay.</p> <p>8 Q. We'll spend a little time</p> <p>9 with that, sir.</p> <p>10 Now, can I show you -- you</p> <p>11 mentioned before that you learned for the</p> <p>12 first time that Dr. Huncharek listed you</p> <p>13 on the proposal for the study that</p> <p>14 ultimately became the 2007 -- 2003</p> <p>15 meta-analysis, correct?</p> <p>16 MR. HEGARTY: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: That's</p> <p>19 correct.</p> <p>20 BY MR. TISI:</p> <p>21 Q. How did you learn that?</p> <p>22 A. Those were -- it was a</p> <p>23 document that I looked at within the past</p> <p>24 month.</p>	<p style="text-align: right;">Page 140</p> <p>1 on a paper or a proposal where you had</p> <p>2 not been involved?</p> <p>3 A. I have to think about that</p> <p>4 for a minute. Can you give me a few</p> <p>5 minutes?</p> <p>6 Q. How about we come back to</p> <p>7 it, because I don't want you to take a</p> <p>8 few minutes.</p> <p>9 A. Okay.</p> <p>10 Q. But can you think of any as</p> <p>11 you sit here right now?</p> <p>12 A. So not off the top of my</p> <p>13 head.</p> <p>14 Q. Okay.</p> <p>15 MR. TISI: What exhibit are</p> <p>16 we up to?</p> <p>17 (Document marked for</p> <p>18 identification as Exhibit</p> <p>19 Muscat-7.)</p> <p>20 BY MR. TISI:</p> <p>21 Q. Now, I'm going to show you</p> <p>22 what I'd like to have marked as Exhibit</p> <p>23 Number 7, which I think is the document</p> <p>24 you're referring to. This is a research</p>
<p style="text-align: right;">Page 139</p> <p>1 Q. Okay. Did you spoke to --</p> <p>2 did you speak to Dr. Huncharek about it</p> <p>3 when you spoke to him recently?</p> <p>4 A. I haven't spoken with him</p> <p>5 since I learned about that information.</p> <p>6 Q. Do you know what the term</p> <p>7 "gifting authorship" is, have you heard</p> <p>8 of that term?</p> <p>9 A. No.</p> <p>10 Q. Have you ever seen</p> <p>11 Dr. Huncharek put your name down on a</p> <p>12 paper where you had no idea of knowing</p> <p>13 what it -- that you had been involved?</p> <p>14 MR. HUDSON: Objection to</p> <p>15 form.</p> <p>16 MR. SILVER: Objection to</p> <p>17 form.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Ever happen before? I'm</p> <p>20 sorry.</p> <p>21 A. I don't understand the</p> <p>22 question. Can you repeat it?</p> <p>23 Q. Had you ever had that happen</p> <p>24 before, where somebody put your name down</p>	<p style="text-align: right;">Page 141</p> <p>1 proposal. Is this the document you'd</p> <p>2 seen?</p> <p>3 A. I can't recall specifically.</p> <p>4 Q. Okay. But let me ask you</p> <p>5 this. This is a letter dated October 12,</p> <p>6 2000?</p> <p>7 A. Mm-hmm.</p> <p>8 Q. And it's a research proposal</p> <p>9 from Dr. Huncharek. Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And it's entitled, Two</p> <p>12 Copies of Our Proposal Regarding Cosmetic</p> <p>13 Talc and Ovarian Cancer?</p> <p>14 A. Yes.</p> <p>15 Q. And it provides a timeline</p> <p>16 and a budget?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And it asks the</p> <p>19 company for feedback, do you see that?</p> <p>20 A. Yes.</p> <p>21 Q. And attached to it is, in</p> <p>22 fact, a research proposal?</p> <p>23 A. Yes.</p> <p>24 Q. Presented to Johnson &amp;</p>



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<p style="text-align: right;">Page 142</p> <p>1 Johnson. Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And it lists Dr. Huncharek,</p> <p>4 correct?</p> <p>5 A. That's correct.</p> <p>6 Q. And it lists Joshua Muscat,</p> <p>7 a senior scientist, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And if you actually</p> <p>10 go to the back, it actually lists a</p> <p>11 budget. Page 21.</p> <p>12 A. Okay.</p> <p>13 Q. Do you see that?</p> <p>14 A. Mm-hmm.</p> <p>15 Q. And you had never seen that</p> <p>16 document before the past month?</p> <p>17 A. That's correct.</p> <p>18 Q. Never at all?</p> <p>19 A. Never.</p> <p>20 Q. You never talked about it</p> <p>21 with Dr. Huncharek, never learned about</p> <p>22 it from Dr. Hopkins or anybody else?</p> <p>23 A. That's correct.</p> <p>24 Q. This came as a complete</p>	<p style="text-align: right;">Page 144</p> <p>1 November 2000. Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And this says, "Perineal</p> <p>4 talc exposure: Preliminary analysis of a</p> <p>5 meta-analysis."</p> <p>6 Do you see that?</p> <p>7 A. Yes, I do.</p> <p>8 Q. And, in fact, is this the</p> <p>9 document that you saw?</p> <p>10 A. The one you just showed me?</p> <p>11 Q. Have you seen this before?</p> <p>12 A. No.</p> <p>13 Q. You never saw this before?</p> <p>14 A. Oh, sorry. I think I saw</p> <p>15 this within the last month.</p> <p>16 Q. If you look at the very last</p> <p>17 page. There's a chart entitled</p> <p>18 Dose-Response Data?</p> <p>19 A. Mm-hmm.</p> <p>20 Q. I'm going to tell you it's</p> <p>21 exactly the same dose-response data that</p> <p>22 was reported in the 2003 article that was</p> <p>23 republished again in your 2011 article.</p> <p>24 Let me ask you this</p>
<p style="text-align: right;">Page 143</p> <p>1 surprise?</p> <p>2 A. Yes.</p> <p>3 Q. Do you know that preliminary</p> <p>4 data on this study was actually sent to</p> <p>5 Johnson &amp; Johnson?</p> <p>6 MR. HUDSON: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: I'm unaware of</p> <p>9 the circumstances of this.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Okay. Have you seen any</p> <p>12 preliminary data related to this article?</p> <p>13 A. I have seen some -- another</p> <p>14 piece of correspondence regarding this.</p> <p>15 I don't remember.</p> <p>16 Q. Let me show you. I'm going</p> <p>17 to show you what I'd like to have marked</p> <p>18 as Exhibit Number 03 -- I'm sorry.</p> <p>19 Exhibit Number 8.</p> <p>20 (Document marked for</p> <p>21 identification as Exhibit</p> <p>22 Muscat-8.)</p> <p>23 BY MR. TISI:</p> <p>24 Q. And this is dated</p>	<p style="text-align: right;">Page 145</p> <p>1 question. Had you seen this data in</p> <p>2 2003?</p> <p>3 MR. HEGARTY: Objection to</p> <p>4 form.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Or 2000 -- 2000?</p> <p>7 MR. HEGARTY: Same</p> <p>8 objection.</p> <p>9 THE WITNESS: No.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Now, collectively, going</p> <p>12 back to this list of articles, I was</p> <p>13 going to go through each one. But I</p> <p>14 really want to get to some other things.</p> <p>15 So you wrote an article in</p> <p>16 1997, 1998, 2000, 2003, 2005, 2007, 2008,</p> <p>17 2009, 2011. Do you see all those here?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. Some of them are</p> <p>20 articles, six of them are articles, and I</p> <p>21 believe -- excuse me. Seven of them are</p> <p>22 articles, two of them are reports,</p> <p>23 correct?</p> <p>24 MR. HEGARTY: Objection to</p>

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<p style="text-align: right;">Page 146</p> <p>1 form.</p> <p>2 THE WITNESS: I'll take your</p> <p>3 word for it.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay. The two reports are</p> <p>6 the National Toxicology Report dated</p> <p>7 2000, and that's Number 3?</p> <p>8 A. That's correct.</p> <p>9 Q. Okay. And the one that you</p> <p>10 did with Dr. Huncharek for the opposing a</p> <p>11 warning on talc is Number 8. That was</p> <p>12 filed in 2009.</p> <p>13 MR. HUDSON: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: 2008, I'm</p> <p>16 sorry. 2009.</p> <p>17 BY MR. TISI:</p> <p>18 Q. It was actually sent -- it</p> <p>19 was -- it was drafted in 2008. It was</p> <p>20 actually filed with the FDA in 2009.</p> <p>21 A. Okay.</p> <p>22 Q. Does that sound right?</p> <p>23 A. I don't know when it was</p> <p>24 filed with the FDA.</p>	<p style="text-align: right;">Page 148</p> <p>1 Q. But the published article is</p> <p>2 derived from these comments, correct?</p> <p>3 MR. HUDSON: Objection to</p> <p>4 form.</p> <p>5 BY MR. TISI:</p> <p>6 Q. It's almost verbatim.</p> <p>7 A. So I haven't gone back and</p> <p>8 compared it, but --</p> <p>9 Q. There are sentences --</p> <p>10 A. Okay.</p> <p>11 Q. The sentences -- there are</p> <p>12 some sentences that differ, but it is --</p> <p>13 essentially, we can go back and compare</p> <p>14 it --</p> <p>15 A. Okay.</p> <p>16 Q. You agree that this article,</p> <p>17 this, this comment that you sent to the</p> <p>18 FDA was edited a little bit, but -- but</p> <p>19 actually appeared in the peer-reviewed</p> <p>20 literature as the 2011 article that we</p> <p>21 had listed as Number 9 here?</p> <p>22 MR. HUDSON: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: I haven't -- I</p>
<p style="text-align: right;">Page 147</p> <p>1 Q. But you did do that report?</p> <p>2 A. I didn't write it.</p> <p>3 Q. You didn't write that report</p> <p>4 at all. Who wrote it?</p> <p>5 A. Dr. Huncharek did.</p> <p>6 Q. And you -- you -- did you</p> <p>7 approve of it before it was sent?</p> <p>8 A. I looked at it.</p> <p>9 Q. You looked at it. You</p> <p>10 actually met with Johnson &amp; Johnson. You</p> <p>11 actually went to New Jersey to talk about</p> <p>12 this study --</p> <p>13 A. Yes, that's correct.</p> <p>14 Q. -- correct?</p> <p>15 And actually, not only that,</p> <p>16 this study was actually published as, in</p> <p>17 large part, as part of the article that's</p> <p>18 Number 9, in other words the 2011</p> <p>19 article, correct?</p> <p>20 MR. HUDSON: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: Yeah. It's a</p> <p>23 published article, yeah.</p> <p>24 BY MR. TISI:</p>	<p style="text-align: right;">Page 149</p> <p>1 haven't done that side-by-side</p> <p>2 comparison.</p> <p>3 BY MR. TISI:</p> <p>4 Q. Okay. You know that's true,</p> <p>5 right?</p> <p>6 MR. HUDSON: Objection to</p> <p>7 form.</p> <p>8 BY MR. TISI:</p> <p>9 Q. You can look -- you can look</p> <p>10 at them and take random notes and look</p> <p>11 and compare the two. There is a</p> <p>12 90 percent overlap between those --</p> <p>13 between those two -- that report and that</p> <p>14 article.</p> <p>15 MR. HEGARTY: Objection to</p> <p>16 form.</p> <p>17 BY MR. TISI:</p> <p>18 Q. I'll represent that to be</p> <p>19 the case.</p> <p>20 A. Okay.</p> <p>21 Q. Okay? Do you have any</p> <p>22 reason to disbelieve me here?</p> <p>23 MR. HUDSON: Objection to</p> <p>24 form.</p>



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<p style="text-align: right;">Page 150</p> <p>1 MR. HEGARTY: Objection to</p> <p>2 form.</p> <p>3 THE WITNESS: I take you as</p> <p>4 an honorable man, yes.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Okay. And I'm going to tell</p> <p>7 you that the 2011 article is almost,</p> <p>8 almost verbatim. There are some</p> <p>9 sentences here or there that are</p> <p>10 different. But almost verbatim what was</p> <p>11 sent to the FDA.</p> <p>12 A. Okay.</p> <p>13 Q. Do you know why it was</p> <p>14 published, the report was published?</p> <p>15 MR. HEGARTY: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: Because it was</p> <p>18 submitted for publication?</p> <p>19 BY MR. TISI:</p> <p>20 Q. Yeah, why was it submitted</p> <p>21 for publication, the report that you sent</p> <p>22 to the FDA?</p> <p>23 MR. HEGARTY: Objection to</p> <p>24 form.</p>	<p style="text-align: right;">Page 152</p> <p>1 tell me why that 2011 article doesn't</p> <p>2 appear on your CV?</p> <p>3 A. So I update my CV periodic.</p> <p>4 Sometimes I miss things, okay. So</p> <p>5 when --</p> <p>6 Q. Well, you said you -- well,</p> <p>7 let me stop you there --</p> <p>8 A. Yeah --</p> <p>9 MR. HUDSON: Let him finish</p> <p>10 his answer, please.</p> <p>11 THE WITNESS: Let me finish.</p> <p>12 Okay.</p> <p>13 BY MR. TISI:</p> <p>14 Q. You said you update your CV</p> <p>15 religiously every week, I think you said</p> <p>16 earlier.</p> <p>17 A. I do.</p> <p>18 Q. Okay. And when you do that,</p> <p>19 and you actually updated your CV for the</p> <p>20 purposes of making sure that I had a</p> <p>21 complete understanding of your</p> <p>22 professional activities, because you</p> <p>23 updated it in July of 2008, correct?</p> <p>24 A. That's correct.</p>
<p style="text-align: right;">Page 151</p> <p>1 THE WITNESS: You'd have to</p> <p>2 ask Dr. Huncharek that. I mean he</p> <p>3 was the lead author.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Okay. Did you communicate</p> <p>6 with him about it?</p> <p>7 A. Hardly.</p> <p>8 Q. Hardly?</p> <p>9 A. Yeah.</p> <p>10 Q. So basically, he submitted</p> <p>11 it for publication without your -- with</p> <p>12 your -- without your knowledge?</p> <p>13 A. No, I was aware of it.</p> <p>14 Q. Okay. Did you approve of</p> <p>15 that?</p> <p>16 A. Yeah, I mean I looked at it</p> <p>17 and said sure.</p> <p>18 Q. Okay. Did you have any</p> <p>19 problem with any of the data compilations</p> <p>20 that were in the -- that were in that</p> <p>21 article?</p> <p>22 A. I looked at it, the report</p> <p>23 looked okay with me.</p> <p>24 Q. Does it surprise -- can you</p>	<p style="text-align: right;">Page 153</p> <p>1 Q. Okay. And one of the things</p> <p>2 that's missing from your CV is the 2011</p> <p>3 article. Can you tell me why that is?</p> <p>4 A. That's an oversight.</p> <p>5 Q. Okay. Now, I went through</p> <p>6 the dates on this. But you wrote fairly</p> <p>7 consistently from the 1990s about issues</p> <p>8 related to talc.</p> <p>9 MR. HUDSON: Objection to</p> <p>10 form.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Correct?</p> <p>13 A. Well, you see where I have</p> <p>14 publications. So, right.</p> <p>15 Q. Right. And the point of</p> <p>16 writing these articles was to express</p> <p>17 your views in the debate about talc and</p> <p>18 ovarian cancer?</p> <p>19 A. That's correct.</p> <p>20 Q. And your point of view,</p> <p>21 broadly speaking, was the same as</p> <p>22 Dr. Huncharek's, that there was an</p> <p>23 association seen in some of the studies,</p> <p>24 but that there was no evidence of a</p>



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<p>1 causal relationship?</p> <p>2 MR. HUDSON: Objection to</p> <p>3 form.</p> <p>4 MR. HEGARTY: Objection.</p> <p>5 THE WITNESS: No.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Okay. Can you think of any</p> <p>8 areas where you and Dr. Huncharek</p> <p>9 disagreed?</p> <p>10 MR. HEGARTY: Objection to</p> <p>11 form.</p> <p>12 THE WITNESS: I'm not sure</p> <p>13 the case ever came up where, you</p> <p>14 know, he looked at my articles and</p> <p>15 I looked at his articles and we</p> <p>16 entered into a discussion.</p> <p>17 He did the meta-analysis on</p> <p>18 ovarian cancer, and he published</p> <p>19 articles.</p> <p>20 And quite frankly, I was</p> <p>21 surprised -- I had no knowledge of</p> <p>22 it. I had no knowledge it was</p> <p>23 done. But that wasn't my -- that</p> <p>24 wasn't my field, meta-analysis.</p>	<p>1 the overall purpose was to debate</p> <p>2 the causal inference.</p> <p>3 The overall purpose was to</p> <p>4 review the literature.</p> <p>5 Ultimately, you know, does</p> <p>6 that bear into the question of</p> <p>7 whether there's a causal</p> <p>8 inference? I mean of course, it's</p> <p>9 a scientific review.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Right. And you're --</p> <p>12 A. But I -- I didn't do a</p> <p>13 review and just say well, I don't think</p> <p>14 it causes cancer or it does cause cancer.</p> <p>15 My purpose of my review, which I did way</p> <p>16 back in 2000, which I was really happy</p> <p>17 about, by the way. I think it was a</p> <p>18 really -- real good review, was to</p> <p>19 critically review the literature, which</p> <p>20 no one had done. That's -- that's why I</p> <p>21 had written that. And to go over the --</p> <p>22 the topical areas that I thought were</p> <p>23 important in terms of interpreting</p> <p>24 literature.</p>
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<p>1 So I'm not actively looking and</p> <p>2 reading his conclusions.</p> <p>3 I wouldn't be surprised if</p> <p>4 there were areas that we agreed</p> <p>5 on. But I didn't participate in</p> <p>6 that study.</p> <p>7 My initial review I did</p> <p>8 independently without his</p> <p>9 knowledge.</p> <p>10 If we came to the same</p> <p>11 conclusion, that's fine. And if</p> <p>12 we didn't, that's fine as well.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Well, that wasn't my</p> <p>15 question, Doctor.</p> <p>16 A. Yeah.</p> <p>17 Q. Your general point of view</p> <p>18 in expressing these articles was that</p> <p>19 there was -- the evidence argued against</p> <p>20 a causal inference for talc and ovarian</p> <p>21 cancer?</p> <p>22 MR. HEGARTY: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: That wasn't</p>	<p>1 Q. And you concluded, back in</p> <p>2 2000 and it's expressed in your writing</p> <p>3 since then, that while there may be</p> <p>4 evidence of an association seen in some</p> <p>5 studies, that that does not, in your</p> <p>6 view, establish a causal link between</p> <p>7 ovarian cancer and cosmetic talc?</p> <p>8 MR. HEGARTY: Objection to</p> <p>9 form. Asked and answered.</p> <p>10 THE WITNESS: That's</p> <p>11 correct.</p> <p>12 BY MR. TISI:</p> <p>13 Q. And you wrote these articles</p> <p>14 to express that point of view to the</p> <p>15 medical and scientific community,</p> <p>16 correct?</p> <p>17 MR. HEGARTY: Objection to</p> <p>18 form.</p> <p>19 THE WITNESS: I wrote those</p> <p>20 articles to express my viewpoint.</p> <p>21 BY MR. TISI:</p> <p>22 Q. And you expressed them to</p> <p>23 the FDA, correct?</p> <p>24 MR. HEGARTY: Objection to</p>

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<p style="text-align: right;">Page 158</p> <p>1 form.</p> <p>2 BY MR. TISI:</p> <p>3 Q. In the content -- in the</p> <p>4 context of the Citizen's Petition</p> <p>5 comments, correct, in 2009?</p> <p>6 A. It was submitted to the FDA.</p> <p>7 Q. And you expressed it in the</p> <p>8 NTP process, correct, which referred --</p> <p>9 resulted in a deferral of the question,</p> <p>10 correct?</p> <p>11 MR. HEGARTY: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: It was</p> <p>14 submitted to the NTP, that's</p> <p>15 correct.</p> <p>16 BY MR. TISI:</p> <p>17 Q. And the whole purpose was</p> <p>18 to -- was to inject your point of view</p> <p>19 into the debate about cosmetic talc and</p> <p>20 ovarian cancer?</p> <p>21 MR. HUDSON: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: I was not</p> <p>24 doing this to debate anybody,</p>	<p style="text-align: right;">Page 160</p> <p>1 I'm going to put a slide here. And we're</p> <p>2 going to work on it together.</p> <p>3 And it is a chart. If I can</p> <p>4 get it to fit.</p> <p>5 It is entitled Joshua</p> <p>6 Muscat, Ph.D., Consulting on Ovarian</p> <p>7 Cancer -- Talc and Ovarian Cancer.</p> <p>8 Do you see that?</p> <p>9 A. Yes, I do.</p> <p>10 Q. Okay. And across the -- I</p> <p>11 guess this is the X axis on the top,</p> <p>12 correct?</p> <p>13 A. That's correct.</p> <p>14 Q. Is the different people who</p> <p>15 we've talked about here. So let's be</p> <p>16 clear.</p> <p>17 The manufacturer of the</p> <p>18 talcum powder products that we are</p> <p>19 talking about, Johnson's Baby Powder and</p> <p>20 Shower to Shower, is Johnson &amp; Johnson</p> <p>21 and you know that to be the case,</p> <p>22 correct?</p> <p>23 A. That's correct.</p> <p>24 Q. All right. The talc</p>
<p style="text-align: right;">Page 159</p> <p>1 okay.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Okay.</p> <p>4 A. It was -- I was doing this</p> <p>5 to express my scientific views on the</p> <p>6 topic.</p> <p>7 Q. Now, I want to move to the</p> <p>8 next topic, which is -- I want to talk</p> <p>9 about your connections with the</p> <p>10 defendants more fulsomely. I mentioned</p> <p>11 it before. And we're going to go through</p> <p>12 it a little bit more in detail.</p> <p>13 A. Okay.</p> <p>14 Q. We talked about your</p> <p>15 publications. Now I want to talk a</p> <p>16 little bit about your -- your connections</p> <p>17 with the different defendants who are</p> <p>18 seated around this table. Okay?</p> <p>19 A. Okay.</p> <p>20 Q. I'll come back to your</p> <p>21 articles after we're done with this. But</p> <p>22 I want the judge and jury to understand a</p> <p>23 little bit about what your role was.</p> <p>24 So I'm going to bring up --</p>	<p style="text-align: right;">Page 161</p> <p>1 supplier is Luzenac or Imerys as it</p> <p>2 was -- Imerys as it's known but it was</p> <p>3 also known as Luzenac and Rio Tinto,</p> <p>4 correct?</p> <p>5 MR. SILVER: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: That's</p> <p>8 correct.</p> <p>9 BY MR. TISI:</p> <p>10 Q. The trade organization we've</p> <p>11 talked about before, is CTFA or PCPC.</p> <p>12 A. Okay.</p> <p>13 Q. They changed their names as</p> <p>14 well, correct?</p> <p>15 A. Okay. Right.</p> <p>16 Q. All right. Then the mining</p> <p>17 trade organization, we really haven't</p> <p>18 talked about them at all, but you</p> <p>19 understand the Industrial Minerals</p> <p>20 Association or IMA, do you know those --</p> <p>21 A. Yes.</p> <p>22 Q. You've heard of those?</p> <p>23 A. Yes.</p> <p>24 Q. Okay. They represent</p>



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<p style="text-align: right;">Page 162</p> <p>1 miners, correct?</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 BY MR. TISI:</p> <p>5 Q. The mining companies?</p> <p>6 MR. HEGARTY: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: I would assume</p> <p>9 so.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Okay. And then I'm going to</p> <p>12 draw a big line here. And then we're</p> <p>13 going to have the lawyers. Right? The</p> <p>14 lawyers who represent them, because they</p> <p>15 were involved in some of these</p> <p>16 discussions as well, correct?</p> <p>17 A. Yes.</p> <p>18 Q. All right. So we are going</p> <p>19 to have outside counsel. Crowell &amp;</p> <p>20 Moring, you mentioned that company,</p> <p>21 correct, that law firm, correct?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And that's where</p> <p>24 Ridge Hall was?</p>	<p style="text-align: right;">Page 164</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And then in 2011,</p> <p>3 2000 to 2011, that's the general time</p> <p>4 frame that you were also a senior</p> <p>5 scientist with MRG, correct?</p> <p>6 MR. HUDSON: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: I wouldn't use</p> <p>9 that term "senior scientist."</p> <p>10 BY MR. TISI:</p> <p>11 Q. Well, you saw that -- that</p> <p>12 reference?</p> <p>13 A. Right. Right. Right.</p> <p>14 Okay.</p> <p>15 Q. Okay. Now, let's talk about</p> <p>16 Johnson &amp; Johnson first. From my review,</p> <p>17 and we talked about this briefly, you</p> <p>18 both became involved with Johnson &amp;</p> <p>19 Johnson and talcum powder products</p> <p>20 through American Health Foundation,</p> <p>21 correct?</p> <p>22 A. That's correct.</p> <p>23 Q. And from my reading of the</p> <p>24 documents, that appears to be in the 1994</p>
<p style="text-align: right;">Page 163</p> <p>1 A. Yes.</p> <p>2 Q. I'm going to write that name</p> <p>3 here. And we are also going to have Bob</p> <p>4 Glenn, right, he worked with them,</p> <p>5 correct? Consultant?</p> <p>6 A. With Crowell &amp; Moring?</p> <p>7 Q. That's correct.</p> <p>8 A. That's correct.</p> <p>9 Q. And he was actually a former</p> <p>10 president of IMA North America, you know</p> <p>11 that to be the case, correct?</p> <p>12 A. I remember he had a</p> <p>13 recognized title. I don't remember what</p> <p>14 it was. But that sounds correct.</p> <p>15 Q. Okay. And then the outside</p> <p>16 lawyers, litigation lawyers, Mr. Hegarty,</p> <p>17 and Ms. Frazier we talked about before,</p> <p>18 are Shook Hardy &amp; Bacon, correct?</p> <p>19 A. Yes, mm-hmm.</p> <p>20 Q. And then along the X axis</p> <p>21 here is the 1990s, and I chose that time</p> <p>22 frame because that's the time you worked</p> <p>23 with the American Health Foundation,</p> <p>24 correct?</p>	<p style="text-align: right;">Page 165</p> <p>1 time frame when the American Health</p> <p>2 Foundation received a consulting</p> <p>3 contract, entered into a consulting</p> <p>4 contract with J&amp;J, does that sound</p> <p>5 familiar?</p> <p>6 MR. HEGARTY: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: So I'm not</p> <p>9 familiar with a consulting</p> <p>10 contract.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Okay. Well, do you</p> <p>13 understand that with Dr. Wynder, you were</p> <p>14 working with Dr. Wynder as his</p> <p>15 subordinate or colleague with Johnson &amp;</p> <p>16 Johnson, but he was the main contact?</p> <p>17 A. So, just for the record,</p> <p>18 actually his name is pronounced Wynder.</p> <p>19 Q. Okay.</p> <p>20 A. Okay. I'm sorry.</p> <p>21 It came through me -- in</p> <p>22 terms of that relationship, came through</p> <p>23 me through Dr. Wynder.</p> <p>24 Q. Okay. And you know</p>



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<p>1 Dr. Wynder -- Wynder --</p> <p>2 A. That's okay. Wynder, right.</p> <p>3 Q. Wynder had been in</p> <p>4 communication with Johnson &amp; Johnson,</p> <p>5 correct?</p> <p>6 MR. HEGARTY: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: I don't know</p> <p>9 how -- who was communicating with</p> <p>10 who. So -- right.</p> <p>11 BY MR. TISI:</p> <p>12 Q. 1994 time frame, let's see.</p> <p>13 AHF. I'm going to show you what I'd like</p> <p>14 to have marked as Exhibits Number 9 and</p> <p>15 10.</p> <p>16 (Document marked for</p> <p>17 identification as Exhibit</p> <p>18 Muscat-9.)</p> <p>19 (Document marked for</p> <p>20 identification as Exhibit</p> <p>21 Muscat-10.)</p> <p>22 BY MR. TISI:</p> <p>23 Q. And Mr. -- Dr. Wynder is</p> <p>24 sadly no longer with us, is he?</p>	<p>1 MR. TISI: I apologize.</p> <p>2 Just bear with me.</p> <p>3 MR. HUDSON: Okay. No</p> <p>4 problem.</p> <p>5 MR. TISI: This is</p> <p>6 Number 11. And I'll get to</p> <p>7 Number 9 in a minute.</p> <p>8 11, if you can -- it's 34</p> <p>9 please. 34.</p> <p>10 MR. HEGARTY: He needs a</p> <p>11 copy of 11.</p> <p>12 BY MR. TISI:</p> <p>13 Q. This is a document dated</p> <p>14 June 1st, 1994. Returning, it says,</p> <p>15 consulting agreement with Dr. Ernst</p> <p>16 Wynder, correct?</p> <p>17 A. Yes.</p> <p>18 Q. And it's a consulting</p> <p>19 agreement between Johnson &amp; Johnson and</p> <p>20 Dr. Wynder, do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Does this, at least,</p> <p>23 indicate to you that there was a</p> <p>24 consulting agreement between American</p>
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<p>1 A. That's correct.</p> <p>2 Q. Okay. And this is Number 9,</p> <p>3 which is a letter from Dr. Wynder in</p> <p>4 1994. And then --</p> <p>5 MR. TISI: No, no, this is</p> <p>6 not it.</p> <p>7 BY MR. TISI:</p> <p>8 Q. Anyway, do you understand --</p> <p>9 here it says, there is a copy of a</p> <p>10 proposal --</p> <p>11 MR. HEGARTY: Chris, do you</p> <p>12 have copies of this? This</p> <p>13 document?</p> <p>14 MR. TISI: I'm sorry. I'm</p> <p>15 sorry. Let me just back up a</p> <p>16 second.</p> <p>17 (Document marked for</p> <p>18 identification as Exhibit</p> <p>19 Muscat-11.)</p> <p>20 BY MR. TISI:</p> <p>21 Q. I'm going to show you</p> <p>22 Number 11. This one.</p> <p>23 MR. HUDSON: Do you have</p> <p>24 copies for us for 9?</p>	<p>1 Health Foundation and Johnson &amp; Johnson?</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 MR. HUDSON: Objection to</p> <p>5 form.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. TISI:</p> <p>8 Q. And that consulting</p> <p>9 agreement involved actually drafting a --</p> <p>10 now, at this time, just on the timeline,</p> <p>11 Dr. Cramer and others had published about</p> <p>12 the relationship between, or alleged</p> <p>13 relationship between talc and ovarian</p> <p>14 cancer, correct?</p> <p>15 MR. HEGARTY: Objection to</p> <p>16 form.</p> <p>17 BY MR. TISI:</p> <p>18 Q. That was in the published</p> <p>19 literature?</p> <p>20 A. It is in the literature.</p> <p>21 And I don't remember the dates of Cramer.</p> <p>22 Q. 1992.</p> <p>23 A. Okay. Okay.</p> <p>24 Q. Is that right? 1982.</p>

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<p style="text-align: right;">Page 170</p> <p>1 Excuse me.</p> <p>2 A. Okay.</p> <p>3 Q. And so this was some</p> <p>4 12 years later, correct?</p> <p>5 A. Okay. Mm-hmm.</p> <p>6 Q. And one of the things you</p> <p>7 discussed with the company was whether or</p> <p>8 not to actually do a study, correct?</p> <p>9 MR. HUDSON: Objection to</p> <p>10 form.</p> <p>11 THE WITNESS: That's</p> <p>12 correct.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Okay. And were you given</p> <p>15 the task of actually designing a study?</p> <p>16 A. Yes.</p> <p>17 Q. And Exhibit Number 9 is a</p> <p>18 copy of a letter dated October 31st --</p> <p>19 MR. HUDSON: He's already</p> <p>20 got a copy of 9.</p> <p>21 MR. TISI: Okay. Here is</p> <p>22 your copies.</p> <p>23 MR. HUDSON: Thank you.</p> <p>24 BY MR. TISI:</p>	<p style="text-align: right;">Page 172</p> <p>1 And it says, "Proposal for</p> <p>2 case-control study of talcum powder use</p> <p>3 and ovarian cancer."</p> <p>4 Do you see that?</p> <p>5 A. Yes. Mm-hmm.</p> <p>6 Q. And that's what you drafted,</p> <p>7 right?</p> <p>8 A. I think it must be. I</p> <p>9 haven't looked at this since, when it was</p> <p>10 drafted, so 1994.</p> <p>11 Q. And you had a choice when</p> <p>12 you did this -- actually you were meeting</p> <p>13 with -- you went to Skillman and you met</p> <p>14 with people and you talked about the</p> <p>15 issue of ovarian cancer and talc,</p> <p>16 correct?</p> <p>17 A. That's correct.</p> <p>18 Q. All right. And you met with</p> <p>19 Dr. Hopkins, and you met with Dr. Jones,</p> <p>20 and you met with a bunch of people,</p> <p>21 correct?</p> <p>22 A. I met with Jones and</p> <p>23 Hopkins. I don't remember, there's</p> <p>24 probably other people that I don't</p>
<p style="text-align: right;">Page 171</p> <p>1 Q. And this is from the</p> <p>2 American Health Foundation to John -- to</p> <p>3 John Jones of Johnson &amp; Johnson, correct?</p> <p>4 A. Yes.</p> <p>5 Q. And it says, "Please find</p> <p>6 enclosed a copy of our proposal,"</p> <p>7 correct?</p> <p>8 A. Yes.</p> <p>9 Q. And you did, in fact, send a</p> <p>10 proposal, correct?</p> <p>11 A. That's correct.</p> <p>12 Q. Okay. I'm going to hand you</p> <p>13 what I'd like to have marked as</p> <p>14 Number 10.</p> <p>15 Here is a copy of a</p> <p>16 proposal. And this is actually a copy of</p> <p>17 the grant application. And actually if</p> <p>18 you take out -- there's a document that</p> <p>19 should not be in there. It's got a Bates</p> <p>20 37.4. If you can just pull that out.</p> <p>21 That shouldn't be in there, I don't</p> <p>22 think.</p> <p>23 I meant to do that last</p> <p>24 night.</p>	<p style="text-align: right;">Page 173</p> <p>1 remember.</p> <p>2 Q. And you could have designed</p> <p>3 any kind of study you wanted, right? You</p> <p>4 could have proposed any kind of study,</p> <p>5 right?</p> <p>6 MR. HEGARTY: Objection.</p> <p>7 BY MR. TISI:</p> <p>8 Q. And there are different</p> <p>9 kinds of epidemiology studies, correct?</p> <p>10 A. That's correct.</p> <p>11 Q. Okay. You could have</p> <p>12 proposed a cohort study, for example?</p> <p>13 A. Yes.</p> <p>14 Q. You could have proposed a</p> <p>15 prospective study -- a prospective study</p> <p>16 of some kind, correct?</p> <p>17 A. There's different study</p> <p>18 designs.</p> <p>19 Q. You could have proposed a</p> <p>20 hospital study, correct?</p> <p>21 A. There's different study</p> <p>22 designs.</p> <p>23 Q. Right. But you didn't</p> <p>24 propose those kinds of studies. You</p>

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<p>1 proposed a case-control study, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And this is a study that</p> <p>4 was -- if you look at this grant</p> <p>5 application, it was about a -- on page --</p> <p>6 third page in, it was about a \$398,000</p> <p>7 study that you proposed to the company?</p> <p>8 A. Okay.</p> <p>9 Q. Right? Is that right?</p> <p>10 A. Yes.</p> <p>11 Q. That's a study that they</p> <p>12 never did?</p> <p>13 A. That's correct.</p> <p>14 Q. And as the 1990s wore on,</p> <p>15 we're going to say AHF. And we're going</p> <p>16 to put studies, case-control. And that</p> <p>17 was Exhibit Number 10, right?</p> <p>18 Now, the next thing that</p> <p>19 happened is in the 1990s, you had</p> <p>20 communications with Dr. Hopkins about</p> <p>21 other studies that were being published</p> <p>22 in the peer-reviewed medical literature</p> <p>23 that showed an increased risk as well,</p> <p>24 true?</p>	<p>1 MR. TISI: This is Exhibit</p> <p>2 Number 12. We don't have to put</p> <p>3 them up yet. This is Exhibit</p> <p>4 Number 12. This is Number 13.</p> <p>5 And this is Number 14.</p> <p>6 We're not going to bring all</p> <p>7 these up. But I'm going to show</p> <p>8 you.</p> <p>9 BY MR. TISI:</p> <p>10 Q. These are a series of</p> <p>11 letters that went back and forth between</p> <p>12 you and Dr. Hopkins related to the Cook</p> <p>13 paper, correct?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And you see --</p> <p>16 actually you can bring this up.</p> <p>17 MR. TISI: Do you have a</p> <p>18 copy of the Cook paper?</p> <p>19 BY MR. TISI:</p> <p>20 Q. And just for the record, the</p> <p>21 Cook paper was an epidemiology study, you</p> <p>22 know that to be true?</p> <p>23 A. Yes.</p> <p>24 Q. And that study reported</p>
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<p>1 A. Not that I could recall.</p> <p>2 Q. Do you remember</p> <p>3 communications about the Cook paper?</p> <p>4 A. I might have sent him a Cook</p> <p>5 paper.</p> <p>6 Q. Do you remember him -- you</p> <p>7 and him talking about how the best way to</p> <p>8 raise questions about that paper?</p> <p>9 MR. HEGARTY: Objection to</p> <p>10 form.</p> <p>11 THE WITNESS: I don't have a</p> <p>12 specific recollection of that.</p> <p>13 (Document marked for</p> <p>14 identification as Exhibit</p> <p>15 Muscat-12.)</p> <p>16 BY MR. TISI:</p> <p>17 Q. Okay. Let me show you</p> <p>18 Exhibits Number 12, 13 and 14.</p> <p>19 (Document marked for</p> <p>20 identification as Exhibit</p> <p>21 Muscat-13.)</p> <p>22 (Document marked for</p> <p>23 identification as Exhibit</p> <p>24 Muscat-14.)</p>	<p>1 about a 1.5 or 50 percent increased risk</p> <p>2 of ovarian cancer seen in women using</p> <p>3 talcum powder products?</p> <p>4 MR. HEGARTY: Objection to</p> <p>5 form.</p> <p>6 MR. HUDSON: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: Okay. So I</p> <p>9 don't have it in front of me. But</p> <p>10 I'll take your word for it.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Okay. And we're going to</p> <p>13 mark it so that the -- so the jury has</p> <p>14 it.</p> <p>15 A. Okay.</p> <p>16 Q. But do you see your letter</p> <p>17 dated March 23, 1997?</p> <p>18 MR. TISI: You can bring</p> <p>19 this up. It's Exhibit 42.</p> <p>20 BY MR. TISI:</p> <p>21 Q. This is Exhibit 14 to our</p> <p>22 deposition dated March 23, 1997. Do you</p> <p>23 see that?</p> <p>24 A. Yes.</p>

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<p style="text-align: right;">Page 178</p> <p>1 Q. Okay. And do you see you 2 are talking about how to respond to the 3 Cook paper? 4 MR. HEGARTY: Objection to 5 form. 6 THE WITNESS: Discussing the 7 Cook paper, right. 8 BY MR. TISI: 9 Q. Right. And one of the 10 things you say here on the first 11 paragraph, the second paragraph says, 12 "One easy way to raise questions 13 regarding these studies in general is to 14 determine the reliability of the 15 questionnaire data on powder use," 16 correct? 17 A. Yes. 18 Q. So you were actually telling 19 Dr. Hopkins, you were giving him a 20 strategy here on how to raise questions 21 about the published study, correct? 22 MR. HEGARTY: Objection to 23 form. 24 MR. HUDSON: Objection to</p>	<p style="text-align: right;">Page 180</p> <p>1 BY MR. TISI: 2 Q. Okay. And one of the 3 questions that you -- one of the things 4 you say, let's raise questions regarding 5 these studies and the reliability of the 6 questionnaire data on powder use, 7 correct? 8 MR. HEGARTY: Objection to 9 form. 10 THE WITNESS: So what I say 11 is one way to raise the questions 12 on these studies is, in general, 13 is to determine the reliability of 14 questionnaire data on powder use, 15 yeah, that's correct. 16 BY MR. TISI: 17 Q. Okay. Just for the record, 18 Exhibit Number 15, I'm going to attach 19 the Cook study. 20 (Document marked for 21 identification as Exhibit 22 Muscat-15.) 23 BY MR. TISI: 24 Q. That's the Cook study to</p>
<p style="text-align: right;">Page 179</p> <p>1 form. 2 THE WITNESS: No. 3 BY MR. TISI: 4 Q. You were not? 5 A. No. 6 Q. So your word, one way to 7 raise questions, you -- what was -- to 8 undermine the -- see how you can 9 undermine the integrity of the studies? 10 MR. HUDSON: Objection to 11 form. 12 THE WITNESS: No. That's 13 not -- no. 14 BY MR. TISI: 15 Q. You don't think so? 16 A. No. 17 Q. You don't think a jury could 18 look at that and see otherwise? 19 MR. HUDSON: Objection to 20 form. 21 MR. SILVER: Objection move 22 to strike. 23 THE WITNESS: I was raising 24 a general principle, okay.</p>	<p style="text-align: right;">Page 181</p> <p>1 which you are referring, correct? 2 Correct? 3 A. Yes. 4 Q. All right. And you, in 5 fact, wrote a letter to the editor about 6 the Cook study, right? 7 A. Yes, that's correct. 8 Q. All right. That was the 9 first article on our list before, 10 correct? 11 A. Yes. 12 Q. Okay. And about the same 13 time, you were talking to Dr. -- you were 14 talking to Dr. Hopkins, correct? 15 MR. HEGARTY: Objection to 16 form. 17 THE WITNESS: So I don't 18 know the exact dates of when I 19 wrote the Cook letter. But within 20 the year, yeah. 21 BY MR. TISI: 22 Q. And it's about the same time 23 you were still waiting for them to spend 24 \$400,000 with your -- with your company</p>

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<p>1 to do a study, correct?</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 THE WITNESS: No.</p> <p>5 BY MR. TISI:</p> <p>6 Q. You were -- I thought you</p> <p>7 said before you still didn't know whether</p> <p>8 or not they were going to fund that</p> <p>9 study, right?</p> <p>10 MR. HUDSON: Objection to</p> <p>11 form. Asked and answered.</p> <p>12 THE WITNESS: This -- this</p> <p>13 was years later. I mean so, so</p> <p>14 many years later that I assume</p> <p>15 that -- no, I remember that we</p> <p>16 were -- we were not being funded</p> <p>17 for that study.</p> <p>18 BY MR. TISI:</p> <p>19 Q. But they never told you</p> <p>20 that, did they?</p> <p>21 A. I don't recall. I think I</p> <p>22 got the message that it was not going to</p> <p>23 be funded. I must have gotten that.</p> <p>24 Q. And that's --</p>	<p>1 Q. Do you remember that?</p> <p>2 A. Not really.</p> <p>3 Q. And just for the record,</p> <p>4 this is the comments on toxicology that</p> <p>5 you wrote.</p> <p>6 (Document marked for</p> <p>7 identification as Exhibit</p> <p>8 Muscat-16.)</p> <p>9 BY MR. TISI:</p> <p>10 Q. We'll mark that as Exhibit</p> <p>11 Number 16. And that corresponds with a</p> <p>12 Number 2 on the -- just for the record,</p> <p>13 it corresponds with Number 2 on our list</p> <p>14 of publications.</p> <p>15 Actually, can I have one</p> <p>16 back, please?</p> <p>17 And you recognize the names,</p> <p>18 Dr. Weiner, Dr. Zazenski, do you remember</p> <p>19 those people?</p> <p>20 MR. SILVER: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: Okay, now I</p> <p>23 remember the names. Yeah.</p> <p>24 BY MR. TISI:</p>
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<p>1 A. Usually, usually, you know,</p> <p>2 in the process of funding, you know</p> <p>3 within several months.</p> <p>4 Q. Now, this is about the time</p> <p>5 you actually wrote in the journal, the</p> <p>6 toxicology journal, The Epidemiology of</p> <p>7 Talc Exposure, correct?</p> <p>8 MR. HEGARTY: Objection to</p> <p>9 form.</p> <p>10 BY MR. TISI:</p> <p>11 Q. That was Document Number 2</p> <p>12 on your -- the exhibit list that we</p> <p>13 talked about, the publications list</p> <p>14 before.</p> <p>15 Do you remember that? And</p> <p>16 you actually -- you remember at that time</p> <p>17 you worked with a Dr. Zazenski. Do you</p> <p>18 know who Dr. Zazenski is?</p> <p>19 A. I know the name.</p> <p>20 MR. SILVER: Objection.</p> <p>21 BY MR. TISI:</p> <p>22 Q. Yeah, he worked -- he worked</p> <p>23 with Imerys, correct?</p> <p>24 A. Okay.</p>	<p>1 Q. Those are people who were</p> <p>2 consultants with Johnson &amp; Johnson and</p> <p>3 Imerys, correct?</p> <p>4 MR. HUDSON: Objection to</p> <p>5 form.</p> <p>6 BY MR. TISI:</p> <p>7 Q. You know -- you know</p> <p>8 Mr. Zazenski worked for Imerys?</p> <p>9 A. No.</p> <p>10 Q. Okay. You know Dr. Weiner</p> <p>11 was a -- was a consultant with Johnson &amp;</p> <p>12 Johnson?</p> <p>13 MR. HEGARTY: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: So I didn't</p> <p>16 know him at the time. But he did</p> <p>17 introduce my -- himself to me when</p> <p>18 he asked me to contribute to the</p> <p>19 article.</p> <p>20 BY MR. TISI:</p> <p>21 Q. And you know he was -- he</p> <p>22 was working with Johnson &amp; Johnson as a</p> <p>23 consultant?</p> <p>24 MR. HEGARTY: Objection to</p>

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<p style="text-align: right;">Page 186</p> <p>1 form.</p> <p>2 THE WITNESS: No, I didn't</p> <p>3 know that.</p> <p>4 BY MR. TISI:</p> <p>5 Q. You didn't know that?</p> <p>6 A. No, I didn't know that.</p> <p>7 Q. Okay. So -- and then in</p> <p>8 2000, the article -- the document with</p> <p>9 your name on it was submitted to Johnson</p> <p>10 &amp; Johnson, correct?</p> <p>11 MR. HUDSON: Objection to</p> <p>12 form.</p> <p>13 BY MR. TISI:</p> <p>14 Q. You talked -- but you didn't</p> <p>15 know about that, that was the proposal</p> <p>16 for the epidemiology meta-analysis from</p> <p>17 Dr. Muscat, remember we looked at that?</p> <p>18 A. Yes.</p> <p>19 MR. HUDSON: Objection to</p> <p>20 form.</p> <p>21 BY MR. TISI:</p> <p>22 Q. Okay. And I'm not going to</p> <p>23 put that on our chart, because I'm just</p> <p>24 not going to, because you said you didn't</p>	<p style="text-align: right;">Page 188</p> <p>1 before.</p> <p>2 (Document marked for</p> <p>3 identification as Exhibit</p> <p>4 Muscat-17.)</p> <p>5 BY MR. TISI:</p> <p>6 Q. I'm going to show you what</p> <p>7 I'd like to have marked as Exhibit</p> <p>8 Number 17.</p> <p>9 MR. TISI: 16?</p> <p>10 MR. HUDSON: 17.</p> <p>11 MR. TISI: 17.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Now, you see this is an</p> <p>14 e-mail, and if you look at the original</p> <p>15 message. It's from John Hopkins, right?</p> <p>16 It's dated October 15, 2000. Do you see</p> <p>17 it? Actually let me refer you to it.</p> <p>18 Okay?</p> <p>19 A. Oh, I see. The original --</p> <p>20 okay.</p> <p>21 Q. Okay. It says from John</p> <p>22 Hopkins?</p> <p>23 A. I see that, okay.</p> <p>24 Q. Okay. And it says, "Dear</p>
<p style="text-align: right;">Page 187</p> <p>1 know about it.</p> <p>2 A. I didn't know about it,</p> <p>3 that's correct.</p> <p>4 Q. Okay. Well, but the next</p> <p>5 thing that happened is you know you were</p> <p>6 proposed to be a speaker or a contributor</p> <p>7 to NTP, correct?</p> <p>8 MR. HUDSON: Objection to</p> <p>9 form.</p> <p>10 THE WITNESS: No. I was</p> <p>11 approached by The Weinberg Group.</p> <p>12 BY MR. TISI:</p> <p>13 Q. But do you know who proposed</p> <p>14 you?</p> <p>15 A. No.</p> <p>16 Q. Do you know it was John</p> <p>17 Hopkins at Johnson &amp; Johnson?</p> <p>18 MR. HEGARTY: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: No, I didn't</p> <p>21 know that.</p> <p>22 BY MR. TISI:</p> <p>23 Q. Had you ever heard that?</p> <p>24 A. I've never heard that</p>	<p style="text-align: right;">Page 189</p> <p>1 Neal, as you probably know, we have a</p> <p>2 telecon later today with CTFA and</p> <p>3 interested parties."</p> <p>4 CTFA is what we know as</p> <p>5 PCPC, right?</p> <p>6 A. Right.</p> <p>7 Q. Okay. "And there is a</p> <p>8 proposal to use The Weinberg Group to</p> <p>9 review/present, cost to be shared I</p> <p>10 guess."</p> <p>11 Do you see that?</p> <p>12 A. I do.</p> <p>13 Q. Okay. "There will be as</p> <p>14 many opinions about the best way to look</p> <p>15 forward. However, my own view is that</p> <p>16 this is not sufficient."</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. "I would propose the</p> <p>20 following additional presenters."</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Number one is Joshua Muscat?</p> <p>24 A. Okay.</p>

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<p style="text-align: right;">Page 190</p> <p>1 Q. Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And that's from John</p> <p>4 Hopkins, correct?</p> <p>5 A. Yes.</p> <p>6 Q. And that's the same John</p> <p>7 Hopkins you were meeting with in the</p> <p>8 1990s?</p> <p>9 MR. HEGARTY: Objection.</p> <p>10 THE WITNESS: I assume so.</p> <p>11 BY MR. TISI:</p> <p>12 Q. And so we can put on our</p> <p>13 timeline here, JH proposes JM. Do you</p> <p>14 see that? And that would be 2000.</p> <p>15 That's correct, right?</p> <p>16 MR. HEGARTY: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: Okay.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Okay. Now the next thing</p> <p>21 that happens, is you actually do get</p> <p>22 contracted by The Weinberg Group to</p> <p>23 prepare that summary, correct?</p> <p>24 A. That's correct.</p>	<p style="text-align: right;">Page 192</p> <p>1 you remember -- okay.</p> <p>2 So 2000, let's put 2000.</p> <p>3 NTP, NTP defers.</p> <p>4 In 2004, NTP raised and</p> <p>5 nominated talc again as a carcinogen,</p> <p>6 correct?</p> <p>7 A. That's correct.</p> <p>8 Q. Okay. 2004. And it was</p> <p>9 called the 12 ROC, 12 report on</p> <p>10 carcinogens, correct?</p> <p>11 A. Okay.</p> <p>12 Q. And we will put 12 next to</p> <p>13 it.</p> <p>14 Now before then,</p> <p>15 Dr. Huncharek of MRG writes his</p> <p>16 meta-analysis, correct?</p> <p>17 MR. HEGARTY: Objection to</p> <p>18 form.</p> <p>19 THE WITNESS: The -- for the</p> <p>20 published paper in 2003, is that</p> <p>21 right?</p> <p>22 BY MR. TISI:</p> <p>23 Q. Yes.</p> <p>24 A. I'm not exactly sure when it</p>
<p style="text-align: right;">Page 191</p> <p>1 Q. And that document is -- oh,</p> <p>2 you actually prepared the report that's</p> <p>3 Number 3 in your -- in the binder that's</p> <p>4 in front of you, correct?</p> <p>5 A. Okay.</p> <p>6 Q. That's the -- that's the</p> <p>7 document that's sent to the National</p> <p>8 Toxicology Project, correct?</p> <p>9 MR. HEGARTY: Objection to</p> <p>10 form.</p> <p>11 THE WITNESS: Program.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Program?</p> <p>14 A. Right.</p> <p>15 Q. Now, in 2003 and 2004, the</p> <p>16 issue came up again, true?</p> <p>17 MR. HEGARTY: Objection to</p> <p>18 form.</p> <p>19 MR. HUDSON: Objection to</p> <p>20 form.</p> <p>21 THE WITNESS: I'm sorry,</p> <p>22 which?</p> <p>23 BY MR. TISI:</p> <p>24 Q. 2003 -- in about 2004, do</p>	<p style="text-align: right;">Page 193</p> <p>1 was written. I know it was -- when it</p> <p>2 was published.</p> <p>3 Q. It was published in 2003.</p> <p>4 A. Right.</p> <p>5 Q. And as a result of the NTP,</p> <p>6 I'm sorry, the NTP -- the renomination,</p> <p>7 you were contacted by Dr. --</p> <p>8 Meta-Analysis Research Group was</p> <p>9 contacted by Dr. Robert Glenn at Crowell</p> <p>10 &amp; Moring to represent and help represent</p> <p>11 Imerys and Johnson &amp; Johnson, correct?</p> <p>12 MR. HUDSON: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: I don't know</p> <p>15 for certain.</p> <p>16 BY MR. TISI:</p> <p>17 Q. But you do -- you know that</p> <p>18 you were retained in the 2004-2005 time</p> <p>19 frame to work on the 12 ROC issue?</p> <p>20 MR. HUDSON: Objection to</p> <p>21 form.</p> <p>22 BY MR. TISI:</p> <p>23 Q. The NTP renomination of</p> <p>24 talc?</p>



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<p>1 A. No.</p> <p>2 Q. You don't know that?</p> <p>3 A. Was I retained to do that,</p> <p>4 no.</p> <p>5 Q. You were retained -- you</p> <p>6 were retained by a law firm, right?</p> <p>7 A. Yes.</p> <p>8 Q. Do you know why it was you</p> <p>9 were retained by a law firm for a</p> <p>10 scientific issue?</p> <p>11 MR. SILVER: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: I didn't have</p> <p>14 active involvement in that. So</p> <p>15 I -- I don't really know the</p> <p>16 circumstances behind what that --</p> <p>17 how that occurred.</p> <p>18 BY MR. TISI:</p> <p>19 Q. I didn't ask you how it</p> <p>20 occurred.</p> <p>21 A. Yeah.</p> <p>22 Q. Did -- did it seem odd to</p> <p>23 you that a law firm would be retaining a</p> <p>24 scientist on scientific issues that were</p>	<p>1 debated in the medical and the scientific</p> <p>2 community at that point in the mid 2000s</p> <p>3 for over 20 years, or at least decades --</p> <p>4 MR. SILVER: Objection to</p> <p>5 form.</p> <p>6 BY MR. TISI:</p> <p>7 Q. -- correct?</p> <p>8 A. So it's a serious medical</p> <p>9 problem.</p> <p>10 Q. And so you understand that</p> <p>11 the issue of whether talc was the cause</p> <p>12 of ovarian cancer was a serious one,</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. And it was one that was</p> <p>16 raised to various regulatory bodies,</p> <p>17 correct?</p> <p>18 MR. HUDSON: Objection to</p> <p>19 form.</p> <p>20 BY MR. TISI:</p> <p>21 Q. It was raised to NTP who</p> <p>22 deferred it in 2000, correct?</p> <p>23 A. That's correct.</p> <p>24 Q. And it was deferred because</p>
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<p>1 pending before a regulatory body like</p> <p>2 NTP?</p> <p>3 MR. SILVER: Objection to</p> <p>4 form.</p> <p>5 MR. HEGARTY: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: I'm not sure</p> <p>8 that I really gave it that much</p> <p>9 thought.</p> <p>10 BY MR. TISI:</p> <p>11 Q. You didn't give it that much</p> <p>12 thought?</p> <p>13 A. No.</p> <p>14 Q. Ovarian cancer is a pretty</p> <p>15 serious disease, is it not?</p> <p>16 A. It is.</p> <p>17 Q. It affects almost 20,000</p> <p>18 women a year, correct?</p> <p>19 A. That's correct.</p> <p>20 Q. It's a serious public health</p> <p>21 issue, correct?</p> <p>22 A. Yes, that's correct.</p> <p>23 Q. And the issue of talc and</p> <p>24 ovarian cancer is something that had been</p>	<p>1 the NTP didn't understand what, as you</p> <p>2 understand it in the federal register, as</p> <p>3 to whether or not -- what was actually</p> <p>4 contained in the bottle of talc, correct?</p> <p>5 MR. SILVER: Objection.</p> <p>6 BY MR. TISI:</p> <p>7 Q. There was a question</p> <p>8 about -- there was a question about the</p> <p>9 definition of talc, correct?</p> <p>10 MR. HUDSON: Form.</p> <p>11 MR. SILVER: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: So I haven't</p> <p>14 read the discussions on why it was</p> <p>15 deferred. I can't really comment</p> <p>16 on it.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Okay. But you know it was</p> <p>19 deferred?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And you know the</p> <p>22 issue came up again in 2000 -- 2004, the</p> <p>23 mid 2000s time frame?</p> <p>24 A. I was not aware of it.</p>



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<p style="text-align: right;">Page 198</p> <p>1 Q. You didn't know that you 2 were being retained in connection with 3 the renomination of talc? 4 MR. HUDSON: Objection to 5 form. 6 THE WITNESS: That's 7 correct. 8 BY MR. TISI: 9 Q. Okay. But you do know that 10 the law firm contacted you at this point, 11 right? 12 MR. HUDSON: Objection to 13 form. 14 MR. SILVER: Objection. 15 THE WITNESS: The law firm 16 had contacted Dr. Huncharek, or 17 Dr. Huncharek contacted the law 18 firm. I don't know the 19 arrangement. 20 BY MR. TISI: 21 Q. Right. But ultimately you 22 were brought into the process, correct? 23 A. That's correct. 24 Q. Okay. And in 2004, you</p>	<p style="text-align: right;">Page 200</p> <p>1 A. Yes. 2 Q. And Ridgway Hall. Ridgway 3 Hall is the -- 4 A. Yes, I see that, right. 5 Q. Ridgway Hall is a senior 6 partner at the law firm of Crowell &amp; 7 Moring. 8 A. That's correct. 9 Q. And I'm going to represent 10 to you, Crowell &amp; Moring is a product 11 liability defense law firm. Do you have 12 any reason to disbelieve that? 13 MR. HUDSON: Objection to 14 form. 15 MR. SILVER: Objection to 16 form. 17 MR. HEGARTY: Objection to 18 form. 19 THE WITNESS: No. 20 BY MR. TISI: 21 Q. You know that they were 22 representing Imerys, correct? 23 A. Yes. It says on the form 24 their client Luzenac America.</p>
<p style="text-align: right;">Page 199</p> <p>1 entered into a contract -- 2 (Document marked for 3 identification as Exhibit 4 Muscat-18.) 5 BY MR. TISI: 6 Q. Let me show you, this is the 7 copy of the contract with Crowell &amp; 8 Moring. 9 MR. HUDSON: Is this 18 or 10 19? 11 MR. TISI: This is 12 Number 18. 13 BY MR. TISI: 14 Q. And this is a document -- 15 MR. HUDSON: Counsel, do you 16 want to change the designation on 17 that? 18 MR. TISI: I'm sorry. Thank 19 you. 20 BY MR. TISI: 21 Q. Number 18 is a contract 22 between Michael Huncharek, Meta-Analysis 23 Research Group, Joshua Muscat, do you see 24 that?</p>	<p style="text-align: right;">Page 201</p> <p>1 Q. Right. And you also know 2 that J&amp;J was paying for part of that 3 funding, correct? 4 MR. HEGARTY: Objection to 5 form. 6 MR. HUDSON: Objection to 7 form. 8 BY MR. TISI: 9 Q. J&amp;J admits that. So you 10 don't have any problem with that. 11 MR. HUDSON: Objection to 12 form. 13 THE WITNESS: Are you asking 14 me at the time of this? 15 BY MR. TISI: 16 Q. Do you know right now that 17 they paid for part of your -- 18 A. I did learn that recently, 19 yes. 20 Q. Okay. And you knew it back 21 then, right? 22 A. No. 23 Q. You never met with -- do you 24 know who Steve Mann was?</p>



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<p>1 A. I know the name now.</p> <p>2 Q. Okay. Did you know it then?</p> <p>3 Did you ever communicate with Steve Mann?</p> <p>4 A. I discovered in one of my</p> <p>5 documents that there was a communication</p> <p>6 between myself and Steve Mann.</p> <p>7 Q. Okay. You know Steve Mann</p> <p>8 is actually cc'd on the bottom of this</p> <p>9 contract, correct?</p> <p>10 A. Yeah, I see that.</p> <p>11 Q. Okay. And Rich Zazenski, he</p> <p>12 is with Imerys, correct, you knew that?</p> <p>13 A. No. At that time --</p> <p>14 Q. You didn't know that?</p> <p>15 A. At these -- no. These names</p> <p>16 didn't mean anything to me.</p> <p>17 Q. Okay. And you also were</p> <p>18 told that your work with the -- with the</p> <p>19 law firm was confidential, true?</p> <p>20 MR. HUDSON: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: I had no</p> <p>23 conversation to that.</p> <p>24 BY MR. TISI:</p>	<p>1 Q. Okay. And the two things</p> <p>2 that were attached to the retainer</p> <p>3 agreement were two projects?</p> <p>4 A. Yes.</p> <p>5 Q. Number one was writing a</p> <p>6 paper for NTP, correct?</p> <p>7 A. Yes.</p> <p>8 Q. And the other one was</p> <p>9 writing a paper -- was writing a paper on</p> <p>10 the -- on -- doing a -- excuse me.</p> <p>11 Doing an analysis on</p> <p>12 diaphragms, correct?</p> <p>13 MR. HEGARTY: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: So one is a</p> <p>16 thorough review of the</p> <p>17 epidemiological literature, and</p> <p>18 the second one is a meta-analysis</p> <p>19 of the diaphragm.</p> <p>20 BY MR. TISI:</p> <p>21 Q. Okay. And the third review</p> <p>22 of the epidemiology literature is the</p> <p>23 paper that ultimately became what was</p> <p>24 called The Critical Review, correct?</p>
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<p>1 Q. I didn't ask you that. You</p> <p>2 knew that the communications between</p> <p>3 Meta-Analysis Research Group, including</p> <p>4 yourself and Dr. Huncharek and anybody</p> <p>5 related to this contract, was</p> <p>6 confidential, correct?</p> <p>7 A. I would assume that to be</p> <p>8 the case.</p> <p>9 Q. Well, you didn't assume it.</p> <p>10 It was in the contract, sir.</p> <p>11 A. Yeah, okay.</p> <p>12 Q. Okay. If you look on the</p> <p>13 second page, there's a whole section on</p> <p>14 confidentiality.</p> <p>15 A. Okay.</p> <p>16 Q. Right? Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. And that all reports should</p> <p>19 be initially submitted as drafts and</p> <p>20 marked as privileged and confidential,</p> <p>21 prepared at the request of legal counsel,</p> <p>22 correct?</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p>	<p>1 MR. SILVER: Objection.</p> <p>2 THE WITNESS: The published</p> <p>3 paper?</p> <p>4 BY MR. TISI:</p> <p>5 Q. Yeah.</p> <p>6 A. No.</p> <p>7 Q. It never became -- the paper</p> <p>8 that you wrote never became The Critical</p> <p>9 Review?</p> <p>10 A. That's correct.</p> <p>11 MR. HUDSON: Objection to</p> <p>12 form.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Are you absolutely sure,</p> <p>15 sir?</p> <p>16 MR. SILVER: Objection.</p> <p>17 THE WITNESS: Yes.</p> <p>18 BY MR. TISI:</p> <p>19 Q. 100 percent?</p> <p>20 MR. HUDSON: Objection to</p> <p>21 form.</p> <p>22 BY MR. TISI:</p> <p>23 Q. 100 percent?</p> <p>24 You never submitted a paper</p>



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<p>1 to be edited by -- edited by -- by the</p> <p>2 law firm and their -- Bob Glenn that</p> <p>3 ultimately became -- The Critical Review?</p> <p>4 MR. HUDSON: Objection to</p> <p>5 form. Asked and answered.</p> <p>6 MR. SILVER: Objection to</p> <p>7 form.</p> <p>8 BY MR. TISI:</p> <p>9 Q. Are you -- are you saying</p> <p>10 that under oath?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. The next question is</p> <p>13 the -- the diaphragm study ultimately</p> <p>14 became published in 2000 -- in fact, I'm</p> <p>15 going to talk about this in a minute. In</p> <p>16 fact, in The Critical Review paper, you</p> <p>17 actually acknowledge Crowell &amp; Moring,</p> <p>18 Inc., did you not?</p> <p>19 A. That's correct.</p> <p>20 Q. Okay. So that was part of</p> <p>21 this process, right?</p> <p>22 MR. HUDSON: Objection to</p> <p>23 form.</p> <p>24 MR. HEGARTY: Objection to</p>	<p>1 Q. They had the same topic?</p> <p>2 A. Yes.</p> <p>3 Q. They had the same language,</p> <p>4 correct?</p> <p>5 A. No.</p> <p>6 Q. The same -- a lot of the</p> <p>7 language overlapped, correct?</p> <p>8 A. There might have been a</p> <p>9 little overlap, but almost all of it was</p> <p>10 completely separate.</p> <p>11 Q. Okay. And then the</p> <p>12 second -- the second article which was</p> <p>13 the diaphragm study --</p> <p>14 A. Yes.</p> <p>15 Q. -- was actually done, and</p> <p>16 actually we'll talk about this, you</p> <p>17 acknowledge that as a grant from -- from</p> <p>18 J&amp;J and Imerys, correct?</p> <p>19 MR. HUDSON: Objection to</p> <p>20 form.</p> <p>21 THE WITNESS: That's what</p> <p>22 was published, that's correct.</p> <p>23 BY MR. TISI:</p> <p>24 Q. Right, that was published.</p>
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<p>1 form.</p> <p>2 MR. SILVER: Objection to</p> <p>3 form.</p> <p>4 THE WITNESS: It was part of</p> <p>5 my disclosure.</p> <p>6 BY MR. TISI:</p> <p>7 Q. I'm not asking you that.</p> <p>8 I'm asking you the study itself. The</p> <p>9 report itself was generated as a result</p> <p>10 of this contract.</p> <p>11 MR. HUDSON: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: No.</p> <p>14 BY MR. TISI:</p> <p>15 Q. It was not. So why did you</p> <p>16 bother acknowledging Crowell &amp; Moring?</p> <p>17 Was it a separate project?</p> <p>18 A. It was a separate project.</p> <p>19 Q. A totally separate project,</p> <p>20 having nothing to do with each other?</p> <p>21 A. They were separate projects.</p> <p>22 Q. Did it have anything to do</p> <p>23 with each other?</p> <p>24 A. They had the same topic.</p>	<p>1 It wasn't a grant, was it? You were paid</p> <p>2 for it by a law firm.</p> <p>3 A grant is a totally</p> <p>4 different process, right?</p> <p>5 MR. SILVER: Objection to</p> <p>6 form.</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 BY MR. TISI:</p> <p>10 Q. A grant is a process where</p> <p>11 you compete to write a -- you submit a</p> <p>12 grant proposal, it's vetted by a</p> <p>13 committee, and a grant is -- a grant is</p> <p>14 either given or not given. That has a</p> <p>15 very special meaning?</p> <p>16 A. Yes.</p> <p>17 MR. HEGARTY: Objection to</p> <p>18 form.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Right. The diaphragm study</p> <p>21 was not that, was it?</p> <p>22 A. So, that's the way it was</p> <p>23 worded.</p> <p>24 Q. But it was wrong, wasn't it?</p>



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<p>1 MR. HUDSON: Objection to 2 form. 3 BY MR. TISI: 4 Q. It was a contract with a law 5 firm, correct? 6 MR. HUDSON: Objection to 7 form. 8 THE WITNESS: It -- I would 9 phrase it as a -- a contract would 10 have been a better use of the word 11 than grant. 12 BY MR. TISI: 13 Q. Okay. Yeah. And Crowell &amp; 14 Moring was not a company, was it, it was 15 a law firm, correct? 16 A. Crowell &amp; Moring is a law 17 firm. 18 Q. Right. And you wrote 19 Crowell &amp; Moring, Inc., correct? 20 A. Yes. 21 Q. And when you wrote this 22 contract with -- when you wrote the 23 meta-analysis from the law firm -- excuse 24 me. The meta-analysis -- the diaphragm</p>	<p>1 MR. HUDSON: Objection to 2 form. 3 MR. SILVER: Objection to 4 form. 5 THE WITNESS: I can't 6 comment on whether the word grant 7 would be used or not. 8 BY MR. TISI: 9 Q. So and then you have -- so 10 you have -- now all during the mid '90s 11 you were having meetings with Johnson &amp; 12 Johnson, correct? 13 MR. HEGARTY: Objection to 14 form. 15 THE WITNESS: No. 16 BY MR. TISI: 17 Q. You had a meeting in 2009 at 18 Skillman to propose additional studies, 19 correct? 20 A. I don't remember the exact 21 date. It was -- 22 Q. January of 2008? 23 A. Okay. Okay. Mm-hmm. 24 Q. Okay. Proposed studies. In</p>
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<p>1 paper was actually a contract with a law 2 firm on behalf of Imerys and Johnson &amp; 3 Johnson, that would have been more 4 accurate, true? 5 MR. HUDSON: Objection to 6 form. 7 THE WITNESS: I'm sorry. 8 I'm not sure what you're saying. 9 More accurate than what? 10 BY MR. TISI: 11 Q. Than writing this was 12 published -- this was published with a 13 grant from J&amp;J and Imerys. This was not 14 a grant proposal, correct? 15 MR. HUDSON: Objection to 16 form. 17 BY MR. TISI: 18 Q. If I had gone to -- if I 19 took this, this contract to the National 20 Institutes of Health who do grants, 21 right? 22 A. Yes. 23 Q. And I presented this, would 24 they say this was a grant?</p>	<p>1 2009, you met with them for the Citizen's 2 Petition? 3 A. Right. 4 Q. 2010, you wrote the -- you 5 actually worked on and published in 2011 6 the paper we talked about, the 2011 paper 7 which was the last paper? 8 A. Right. 9 Q. Okay. And then you became 10 an expert for them in litigation, right? 11 A. That's correct. 12 Q. My handwriting is abysmal. 13 So and -- let me ask you 14 this. Were you paid all during this 15 time? 16 MR. HEGARTY: Objection to 17 form. 18 MR. SILVER: Objection to 19 form. 20 BY MR. TISI: 21 Q. Were you paid for your work 22 at American -- that you did with American 23 Health Foundation? 24 A. I was an employee there.</p>



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<p style="text-align: right;">Page 214</p> <p>1 Q. All right. Did -- did they 2 get money from Johnson &amp; Johnson in 3 connection with your work? 4 MR. HUDSON: Objection to 5 form. 6 THE WITNESS: We were not 7 funded to do that. 8 BY MR. TISI: 9 Q. Right. But you -- but they 10 paid you for your -- for submitting a 11 proposal and meeting with them, and your 12 expenses and all that stuff, going to 13 Skillman, all that thing? 14 MR. HUDSON: Objection. 15 THE WITNESS: I have no 16 knowledge of that. I just, I was 17 an employee, I don't -- I didn't 18 do the billing. I don't know 19 whether Johnson &amp; Johnson paid for 20 our trip to go out there. I have 21 no knowledge of that. 22 BY MR. TISI: 23 Q. But you know you -- you were 24 hoping to get the contract, right?</p>	<p style="text-align: right;">Page 216</p> <p>1 MR. HEGARTY: Objection. 2 MR. SILVER: Objection. 3 BY MR. TISI: 4 Q. They paid to -- you never 5 got any money for any of the work that 6 you did with Meta-Analysis Research 7 Group? 8 If I were to have 9 Dr. Huncharek in that chair right now and 10 say did you pay Dr. Huncharek (sic) for 11 the work that he did on those papers, he 12 would say no? 13 MR. HUDSON: Objection to 14 form. 15 THE WITNESS: I can't answer 16 that. I -- I never submitted any 17 time sheets to him. I was not 18 paid for it. 19 BY MR. TISI: 20 Q. Okay. In this -- in this 21 document here it says you were going to 22 be paid, at one point like \$6,000, et 23 cetera, for your consulting fees and all 24 that?</p>
<p style="text-align: right;">Page 215</p> <p>1 A. Sure. 2 Q. Okay. So about 1994 you 3 were hoping to get funded and then you 4 became -- you were paid for your NTP 5 work. You were paid for your working on 6 that contract with the lawyers, correct? 7 MR. HEGARTY: Objection to 8 form. 9 MR. HUDSON: Objection to 10 form. 11 THE WITNESS: I'm sorry, 12 which contract were you referring 13 to? 14 BY MR. TISI: 15 Q. The contract involving the 16 diaphragm study and The Critical Review? 17 A. No. 18 Q. You weren't paid for that? 19 A. No. 20 Q. It didn't -- you didn't get 21 paid, nobody paid you? 22 A. No. 23 Q. Johnson &amp; Johnson admits 24 that they paid you.</p>	<p style="text-align: right;">Page 217</p> <p>1 A. I see that. 2 MR. HEGARTY: Objection. 3 BY MR. TISI: 4 Q. You never got any of that 5 money? 6 A. No. 7 Q. Really? 8 A. Yes. 9 Q. And your trips back and 10 forth to Skillman, you never got paid for 11 that? 12 A. No. I don't have any 13 recollection of submitting a bill for my 14 trip to Skillman, no. 15 Q. Were you paid as an expert? 16 MR. HUDSON: Objection to 17 form. 18 MR. HEGARTY: Objection to 19 form. 20 THE WITNESS: No. 21 BY MR. TISI: 22 Q. You weren't paid as an 23 expert. You did all this for free, all 24 of it for free?</p>

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<p style="text-align: right;">Page 218</p> <p>1 MR. HEGARTY: Objection to</p> <p>2 form.</p> <p>3 THE WITNESS: I really</p> <p>4 didn't do that much. I went to</p> <p>5 Skillman, that is true.</p> <p>6 BY MR. TISI:</p> <p>7 Q. You had meetings and</p> <p>8 conversations?</p> <p>9 A. Yes.</p> <p>10 Q. You -- by the way, was -- do</p> <p>11 you know whether Dr. Huncharek was paid?</p> <p>12 A. I don't know.</p> <p>13 Q. Okay. Now let's talk about</p> <p>14 Imerys. My friend Mark down there is</p> <p>15 perking up his head.</p> <p>16 Imerys was a company that</p> <p>17 mines talc for cosmetic use. We talked</p> <p>18 about that, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And you first came in</p> <p>21 contact -- did you speak with them at any</p> <p>22 time in the 1990s to your knowledge?</p> <p>23 A. No, I don't believe so.</p> <p>24 Q. So the first contact that</p>	<p style="text-align: right;">Page 220</p> <p>1 Luzenac -- was involved with helping put</p> <p>2 together the packet for the NTP in 2000?</p> <p>3 A. For The Weinberg Group? I</p> <p>4 thought the -- the document you showed me</p> <p>5 suggested my name was nominated by --</p> <p>6 Q. Johnson &amp; Johnson.</p> <p>7 A. Johnson &amp; Johnson.</p> <p>8 Q. But you know that -- do you</p> <p>9 know that Imerys was involved in the</p> <p>10 process of collecting reports for</p> <p>11 presentation to the NTP in 2000?</p> <p>12 MR. HUDSON: Objection to</p> <p>13 form.</p> <p>14 MR. SILVER: Objection to</p> <p>15 form.</p> <p>16 THE WITNESS: No.</p> <p>17 BY MR. TISI:</p> <p>18 Q. You don't know that. Okay.</p> <p>19 But -- so the first</p> <p>20 knowledge you have is in 2005 and 2004</p> <p>21 when the contract was entered into on</p> <p>22 behalf of Imerys to do those two studies?</p> <p>23 A. That's correct.</p> <p>24 Q. The diaphragm study and The</p>
<p style="text-align: right;">Page 219</p> <p>1 you would have had with them to the best</p> <p>2 of your knowledge was in preparation for</p> <p>3 the -- the PC -- or the report on talc to</p> <p>4 the NTP?</p> <p>5 MR. SILVER: Objection to</p> <p>6 form.</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: No.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Okay. That's -- I thought</p> <p>12 you said you understood that Imerys was</p> <p>13 involved with the -- retaining The</p> <p>14 Weinberg Group?</p> <p>15 MR. HUDSON: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: No, I'm sorry,</p> <p>18 can you repeat? That Imerys was</p> <p>19 involved in retaining -- I know</p> <p>20 you just showed me a document.</p> <p>21 BY MR. TISI:</p> <p>22 Q. Yes. Do you remember</p> <p>23 that -- do you remember that we talked</p> <p>24 about Imerys and Luzenac -- I should say</p>	<p style="text-align: right;">Page 221</p> <p>1 Critical Review?</p> <p>2 A. That's correct.</p> <p>3 MR. SILVER: Objection to</p> <p>4 form.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Okay. And you actually, at</p> <p>7 the meetings in Skillman and, et cetera,</p> <p>8 those meetings were meetings where Imerys</p> <p>9 was involved, correct?</p> <p>10 MR. HUDSON: Objection to</p> <p>11 form.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Mr. Zazenski was there,</p> <p>14 other people from Imerys were there. Do</p> <p>15 you recall that?</p> <p>16 A. No, I don't.</p> <p>17 Q. Do you remember</p> <p>18 submitting -- submitting your -- your</p> <p>19 proposed additional studies to people at</p> <p>20 Imerys?</p> <p>21 A. No.</p> <p>22 Q. You don't -- did you have</p> <p>23 any involvement in that at all, preparing</p> <p>24 those study proposals or was that all</p>

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<p>1 Dr. Huncharek?</p> <p>2 A. Those -- those were</p> <p>3 Dr. Huncharek's proposals.</p> <p>4 Q. But your name was on it?</p> <p>5 A. Yes.</p> <p>6 Q. Why would Dr. Huncharek --</p> <p>7 but were you -- did you know that they</p> <p>8 were being submitted with your name on</p> <p>9 it?</p> <p>10 A. I think I was aware of it.</p> <p>11 Q. You think you were aware of</p> <p>12 it. You went to the meetings.</p> <p>13 A. Yes.</p> <p>14 Q. I mean he wasn't hiding it</p> <p>15 from you, was he?</p> <p>16 A. No.</p> <p>17 MR. HUDSON: Objection to</p> <p>18 form.</p> <p>19 BY MR. TISI:</p> <p>20 Q. And you don't -- if the</p> <p>21 records reflect that Imerys was at those</p> <p>22 meetings, that wouldn't surprise you,</p> <p>23 would it?</p> <p>24 MR. HEGARTY: Objection to</p>	<p>1 you were paid by The Weinberg Group, but</p> <p>2 we know it was submitted, your report was</p> <p>3 submitted on behalf of CTFA, correct?</p> <p>4 A. That's correct.</p> <p>5 Q. Do you know who Linda Loretz</p> <p>6 is?</p> <p>7 A. I know the name has come up.</p> <p>8 I -- I can't remember. The name sounds</p> <p>9 familiar. I can't really remember who</p> <p>10 she is.</p> <p>11 Q. Okay. Do you know that they</p> <p>12 were -- and -- and the Citizen's Petition</p> <p>13 in 2009 was submitted under PCPC's name</p> <p>14 as well, correct?</p> <p>15 A. That's correct.</p> <p>16 Q. You forgot one important</p> <p>17 point. You attended the IARC proceedings</p> <p>18 in France, correct?</p> <p>19 A. That's correct.</p> <p>20 Q. And you initially were</p> <p>21 proposed to represent Imerys, correct?</p> <p>22 MR. HEGARTY: Objection to</p> <p>23 form.</p> <p>24 MR. SILVER: Objection to</p>
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<p>1 form.</p> <p>2 THE WITNESS: It wouldn't</p> <p>3 surprise me. I don't remember who</p> <p>4 was at those meetings.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Well, the record will</p> <p>7 reflect, I will -- I will make a</p> <p>8 representation to you that at that</p> <p>9 meeting and at the Citizen's Petition</p> <p>10 meeting in November of 2008, Imerys was</p> <p>11 at -- was at all of those.</p> <p>12 MR. HUDSON: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: Okay.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Do you have any reason to</p> <p>17 disbelieve me?</p> <p>18 A. No.</p> <p>19 MR. HUDSON: Objection to</p> <p>20 form.</p> <p>21 BY MR. TISI:</p> <p>22 Q. Okay. CTFA or PCPC, we</p> <p>23 talked about that.</p> <p>24 In 2000 you were retained,</p>	<p>1 form.</p> <p>2 MR. HUDSON: Objection to</p> <p>3 form.</p> <p>4 THE WITNESS: So no, my name</p> <p>5 was nominated to be the --</p> <p>6 initially on the expert panel.</p> <p>7 BY MR. TISI:</p> <p>8 Q. From -- and who nominated</p> <p>9 you?</p> <p>10 A. IMA.</p> <p>11 Q. IMA North America. And you</p> <p>12 were rejected, right?</p> <p>13 A. That's correct.</p> <p>14 Q. And then you went as an</p> <p>15 observer, correct?</p> <p>16 A. I was nominated as observer,</p> <p>17 that's correct.</p> <p>18 Q. Okay. And so that would be</p> <p>19 under this category IMA North America.</p> <p>20 So that would be 2005, nomination for</p> <p>21 panel for IARC, observer.</p> <p>22 Now, the panel included some</p> <p>23 scientists and epidemiologists, correct?</p> <p>24 A. Yes.</p>

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<p>1 Q. Do you know who 2 Dr. Siemietycki? 3 A. I believe he was the chair 4 of the panel. 5 Q. He was the chair of the 6 panel. Do you remember if 7 Dr. Siemietycki -- you made comments 8 about Dr. Siemietycki was the most -- I 9 think you used the word "the most 10 skeptical." Do you remember that phrase? 11 MR. HEGARTY: Objection to 12 form. 13 THE WITNESS: I don't have 14 any specific recollection. Okay. 15 BY MR. TISI: 16 Q. Well, in your interactions 17 with Dr. Siemietycki -- 18 A. Yes. 19 Q. -- was he -- was he -- did 20 he appear to be biased to you? 21 A. No, I don't think so. 22 Q. Did he appear to be -- he's 23 a well known epidemiologist, correct? 24 A. I don't know. I mean, I</p>	<p>1 Yeah, I think so. 2 Q. And Johnson &amp; Johnson was 3 there? 4 MR. HUDSON: Objection to 5 form. 6 THE WITNESS: I don't know. 7 BY MR. TISI: 8 Q. 2005? 9 A. No, I don't think so. 10 Q. You don't think so? 11 A. Johnson &amp; Johnson? I 12 remember Bob Glenn was there. 13 Q. Do you remember having 14 meetings with, and making reports of the 15 proceedings to the talc industry -- 16 MR. HEGARTY: Objection to 17 form. 18 BY MR. TISI: 19 Q. -- who were present? 20 A. There -- there was a group 21 that was sent from the IMA that was 22 there. 23 Q. And it included Johnson &amp; 24 Johnson, did it not?</p>
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<p>1 never met him before. That was my first 2 encounter with him. 3 Q. So you -- 4 A. I don't know if he's well 5 known or not. 6 Q. Okay. 7 A. Right. 8 Q. Now, we talked about Imerys, 9 Crowell &amp; Moring. 10 And, actually, at the IARC 11 proceedings, Bob Glenn was there, right, 12 from the law firm, correct? 13 A. Yes. 14 Q. So had the lawyers go -- the 15 lawyers -- the lawyers' consultant go out 16 with you, correct? 17 MR. HEGARTY: Objection to 18 form. 19 THE WITNESS: Bob Glenn was 20 there. 21 BY MR. TISI: 22 Q. And people from Imerys were 23 there, correct? 24 A. I can't remember the names.</p>	<p>1 MR. HEGARTY: Objection to 2 form. 3 THE WITNESS: I mean, I 4 don't remember. I -- no. I 5 don't -- maybe. 6 BY MR. TISI: 7 Q. And it included Imerys, 8 correct? Mr. Zazenski was there, was he 9 not? 10 A. I honestly can't remember. 11 If you say so, yes. 12 Q. And the Minerals Association 13 was there. They actually were the people 14 that hired you, correct? 15 A. That's correct. 16 Q. Did you disclose to -- you 17 actually had to apply to be an observer 18 to IARC, correct? 19 A. Yes. 20 Q. Okay. Did you disclose that 21 you had done work with Crowell &amp; Moring 22 and you were actually under contract with 23 a law firm representing Imerys and J&amp;J? 24 MR. HEGARTY: Objection to</p>

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<p style="text-align: right;">Page 230</p> <p>1 form.</p> <p>2 THE WITNESS: There was a</p> <p>3 disclosure form that was filled</p> <p>4 out.</p> <p>5 BY MR. TISI:</p> <p>6 Q. And that disclosure form</p> <p>7 doesn't mention J&amp;J or Imerys or</p> <p>8 Crowell &amp; Moring at all, does it?</p> <p>9 A. Yeah, I looked at that.</p> <p>10 Q. And it does not mention it,</p> <p>11 does it?</p> <p>12 A. It mentions IMA. And there</p> <p>13 was a second disclosure about whether I</p> <p>14 worked for tobacco companies.</p> <p>15 Q. Right. But it didn't</p> <p>16 mention J&amp;J, did it?</p> <p>17 A. I didn't put that on the</p> <p>18 form.</p> <p>19 Q. And it was -- and it was --</p> <p>20 you were actually retained by Crowell &amp;</p> <p>21 Moring on behalf of both J&amp;J and Imerys,</p> <p>22 correct?</p> <p>23 MR. HUDSON: Objection to</p> <p>24 form.</p>	<p style="text-align: right;">Page 232</p> <p>1 Q. Did you disclose that you</p> <p>2 were working for -- that you were under</p> <p>3 contract for the -- for the mining</p> <p>4 company?</p> <p>5 A. No.</p> <p>6 Q. Don't you think that that's</p> <p>7 something that people at IARC would want</p> <p>8 to know?</p> <p>9 MR. HUDSON: Objection to</p> <p>10 form.</p> <p>11 THE WITNESS: That's an</p> <p>12 oversight. I disclosed my paid</p> <p>13 consultant -- my paid sponsor,</p> <p>14 Industrial Minerals Association.</p> <p>15 It's true I didn't disclose</p> <p>16 the Crowell &amp; Moring. But I don't</p> <p>17 think it even occurred to me.</p> <p>18 BY MR. TISI:</p> <p>19 Q. You didn't disclose, you</p> <p>20 didn't disclose The Weinberg Group, did</p> <p>21 you?</p> <p>22 A. No.</p> <p>23 Q. You didn't disclose PCPC,</p> <p>24 did you?</p>
<p style="text-align: right;">Page 231</p> <p>1 THE WITNESS: I'm sorry, can</p> <p>2 you repeat that?</p> <p>3 BY MR. TISI:</p> <p>4 Q. Yeah.</p> <p>5 A. Yeah.</p> <p>6 Q. You were actually -- the</p> <p>7 IARC proceedings were in February of</p> <p>8 2005?</p> <p>9 A. Yes. Yes.</p> <p>10 MR. HUDSON: Objection.</p> <p>11 BY MR. TISI:</p> <p>12 Q. And we looked at your</p> <p>13 contract from February 28, 2005, and you</p> <p>14 were actually retained by a law firm on</p> <p>15 behalf of Imerys, and you also understood</p> <p>16 J&amp;J as well, correct?</p> <p>17 MR. HUDSON: Objection to</p> <p>18 form.</p> <p>19 THE WITNESS: So I didn't</p> <p>20 know about J&amp;J.</p> <p>21 BY MR. TISI:</p> <p>22 Q. Okay. Let's talk about</p> <p>23 Imerys?</p> <p>24 A. Okay.</p>	<p style="text-align: right;">Page 233</p> <p>1 A. No.</p> <p>2 MR. LOCKE: Objection to</p> <p>3 form.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Let's talk about the lawyers</p> <p>6 a bit.</p> <p>7 MR. TISI: Can I have 149,</p> <p>8 please. Actually, never mind.</p> <p>9 BY MR. TISI:</p> <p>10 Q. We talked about Crowell &amp;</p> <p>11 Moring. That's the law firm, right?</p> <p>12 A. Yes.</p> <p>13 Q. And you had a contract with</p> <p>14 Crowell &amp; Moring, right?</p> <p>15 MR. HUDSON: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: I signed a</p> <p>18 contract with them, right.</p> <p>19 BY MR. TISI:</p> <p>20 Q. But you claim to have not</p> <p>21 been paid directly or indirectly at all</p> <p>22 for any of the work that you did under</p> <p>23 the contract?</p> <p>24 A. That's correct.</p>



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<p>1 Q. And the contract, just to be 2 clear, was for the -- so this would be 3 2005. And you contract -- and it's for 4 The Critical Review and diaphragm, right? 5 MR. HEGARTY: Objection to 6 form. 7 THE WITNESS: Diaphragm 8 meta-analysis. 9 BY MR. TISI: 10 Q. Correct. Were you ever told 11 by the law firm to make sure that you 12 communicated any information to them to 13 preserve the attorney privileges against 14 disclosure? 15 MR. SILVER: Objection. I'm 16 instructing the witness's counsel 17 to instruct the witness not to 18 answer on the grounds of 19 privilege. Communications with a 20 law firm? Chris, come on. 21 BY MR. TISI: 22 Q. Did you ever understand that 23 you were -- that you were supposed to 24 continue to communicate with the law firm</p>	<p>1 strictly confidential, correct? 2 A. Yes. 3 Q. And you abided by the 4 contract, correct? 5 A. I personally, yes. 6 Q. Did you ever understand from 7 your speaking with anybody involved in 8 this contract that before J&amp;J was willing 9 to fund the studies, they wanted to know 10 whether or not the study would be 11 favorable to their position? 12 MR. HUDSON: Objection to 13 form. 14 THE WITNESS: I'm sorry. I 15 don't understand the question. 16 BY MR. TISI: 17 Q. Did they ever want to know 18 from you what you thought your studies 19 would show before you actually did the 20 studies? 21 MR. HEGARTY: Objection to 22 form. 23 THE WITNESS: Which studies 24 are you referring to?</p>
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<p>1 in order to not disclose information? 2 MR. SILVER: Same 3 instruction to the extent the 4 witness can answer. 5 BY MR. TISI: 6 Q. You are not going to answer 7 that question? 8 A. No. 9 Q. Okay. And you did note, 10 that we talked about before, in your 11 contract with the law firm, there is a 12 provision that everything that you did 13 had to be marked with a little phrase 14 that said attorney work product. Do you 15 remember that? Privileged? 16 MR. SILVER: Objection to 17 form. 18 MR. HEGARTY: Objection to 19 form. 20 MR. HUDSON: Objection to 21 form. 22 THE WITNESS: Yes. 23 BY MR. TISI: 24 Q. Okay. And that it was</p>	<p>1 BY MR. TISI: 2 Q. Either one of them. Any of 3 the studies under the contract. 4 A. No. 5 (Document marked for 6 identification as Exhibit 7 Muscat-19.) 8 BY MR. TISI: 9 Q. I'm going to show you an 10 e-mail dated -- 11 MR. TISI: What number are 12 we at? 13 BY MR. TISI: 14 Q. Here's Number 19. I'll see 15 if I can refresh your recollection here. 16 This is an e-mail dated 17 February 18, 2005. Do you see that? 18 A. Yes. 19 Q. And that was actually before 20 the contract was formally entered into on 21 the 28th of February 2005, correct? 22 A. Yes. 23 Q. Okay. And there's an e-mail 24 that refers to you?</p>

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<p style="text-align: right;">Page 238</p> <p>1 A. Okay.</p> <p>2 Q. It says -- and I'll kind of</p> <p>3 see if I can help you set the table here</p> <p>4 a little bit.</p> <p>5 A. Okay.</p> <p>6 Q. It's to Steven Mann. And</p> <p>7 You know, that he's with J&amp;J, correct?</p> <p>8 A. Yes.</p> <p>9 Q. He is a toxicologist with</p> <p>10 J&amp;J, correct?</p> <p>11 MR. HEGARTY: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: I don't know</p> <p>14 if he's still there or not. But</p> <p>15 right.</p> <p>16 BY MR. TISI:</p> <p>17 Q. And it's from Ridgway Hall,</p> <p>18 who is the senior partner at Crowell &amp;</p> <p>19 Moring correct?</p> <p>20 A. Yes.</p> <p>21 Q. And it's an e-mail that</p> <p>22 says, "In talking to my boss I think it</p> <p>23 would be better that J&amp;J not be mentioned</p> <p>24 in the retainer letter."</p>	<p style="text-align: right;">Page 240</p> <p>1 that Josh expects favorable results from</p> <p>2 the diaphragm/ovarian comparison; thus,</p> <p>3 we should be willing to support this</p> <p>4 study also."</p> <p>5 Do you see that?</p> <p>6 A. Yes, I do.</p> <p>7 Q. Okay. Did you ever</p> <p>8 communicate that you said in 2005, you</p> <p>9 expected results that would be favorable</p> <p>10 to the company?</p> <p>11 MR. HEGARTY: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: No.</p> <p>14 BY MR. TISI:</p> <p>15 Q. So that's a lie?</p> <p>16 MR. HEGARTY: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: I don't know</p> <p>19 whether it's a lie or not. But</p> <p>20 it's just not accurate.</p> <p>21 BY MR. TISI:</p> <p>22 Q. It's not accurate?</p> <p>23 A. Yeah, that's correct.</p> <p>24 Q. But it does say that we</p>
<p style="text-align: right;">Page 239</p> <p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Now, this is the same</p> <p>4 Steven Mann who is cc'd on the retainer</p> <p>5 letter, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And actually, J&amp;J was not on</p> <p>8 the retainer letter, was it?</p> <p>9 MR. HEGARTY: Objection to</p> <p>10 form.</p> <p>11 THE WITNESS: That's</p> <p>12 correct.</p> <p>13 BY MR. TISI:</p> <p>14 Q. "I don't have a definitive</p> <p>15 answer on splitting the cost study yet.</p> <p>16 But that shouldn't hold you up from</p> <p>17 proceeding with Mike and Josh."</p> <p>18 A. See that.</p> <p>19 Q. Mike and Josh is you and</p> <p>20 Mike -- you and --</p> <p>21 A. Dr. Huncharek.</p> <p>22 Q. Huncharek. "However, it's</p> <p>23 my recommendation that Josh" -- I'm</p> <p>24 sorry. "However, it is my recommendation</p>	<p style="text-align: right;">Page 241</p> <p>1 would be willing to support the study,</p> <p>2 correct?</p> <p>3 MR. HEGARTY: Objection to</p> <p>4 form.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Thus, we should be willing</p> <p>7 to support the study.</p> <p>8 A. Yeah, I see that.</p> <p>9 Q. And they did provide support</p> <p>10 for the study, correct?</p> <p>11 MR. HEGARTY: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: They provided</p> <p>14 support for the study.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Correct. And that was --</p> <p>17 when we say support, we're talking about</p> <p>18 financial support, correct?</p> <p>19 A. I would assume so.</p> <p>20 Q. And in fact, you and</p> <p>21 Dr. Huncharek actually drafted two</p> <p>22 papers, correct? Two drafts of papers,</p> <p>23 correct?</p> <p>24 MR. HUDSON: Objection to</p>



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<p style="text-align: right;">Page 242</p> <p>1 form.</p> <p>2 THE WITNESS: He wrote the</p> <p>3 papers.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Boy, you're going a long way</p> <p>6 to try to distance yourself from those</p> <p>7 papers, Doctor?</p> <p>8 A. I'm just stating the facts.</p> <p>9 MR. HEGARTY: Objection to</p> <p>10 form.</p> <p>11 BY MR. TISI:</p> <p>12 Q. He wrote the papers. But</p> <p>13 you -- you looked at the papers before</p> <p>14 they were submitted, correct?</p> <p>15 A. I don't have a specific</p> <p>16 recollection of that, but I probably did.</p> <p>17 Q. Yeah, and they were</p> <p>18 submitted according to the contract with</p> <p>19 Crowell &amp; Moring, the lawyers, on behalf</p> <p>20 of Imerys, the mining company, and J&amp;J,</p> <p>21 the manufacturer of talc? It was</p> <p>22 submitted to the law firm for review and</p> <p>23 comment, correct?</p> <p>24 MR. HEGARTY: Objection to</p>	<p style="text-align: right;">Page 244</p> <p>1 the papers.</p> <p>2 BY MR. TISI:</p> <p>3 Q. I didn't -- okay.</p> <p>4 You knew when you were</p> <p>5 involved with the papers that they were</p> <p>6 going in under your name, first of all</p> <p>7 right?</p> <p>8 A. That's correct.</p> <p>9 Q. Okay. So you knew that you</p> <p>10 were going to be responsible academically</p> <p>11 for the papers, correct?</p> <p>12 A. Not academically. But for</p> <p>13 the contract requirements.</p> <p>14 Q. Okay. And you knew that</p> <p>15 they were submitted to the law firm for</p> <p>16 review and comment, correct?</p> <p>17 A. No, actually.</p> <p>18 Q. You didn't know that?</p> <p>19 A. I didn't have any part of</p> <p>20 that process.</p> <p>21 Q. In the contract it says it</p> <p>22 was to be submitted to the law firm?</p> <p>23 A. I see that.</p> <p>24 Q. You did see that?</p>
<p style="text-align: right;">Page 243</p> <p>1 form.</p> <p>2 MR. HUDSON: Objection to</p> <p>3 form.</p> <p>4 THE WITNESS: I don't know.</p> <p>5 BY MR. TISI:</p> <p>6 Q. You don't know?</p> <p>7 A. I -- I didn't submit</p> <p>8 anything to the law firm.</p> <p>9 Q. You submitted it to</p> <p>10 Dr. Huncharek with the idea that</p> <p>11 Dr. Huncharek was going to submit it to</p> <p>12 the law firm, correct?</p> <p>13 MR. HUDSON: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: I'm sorry.</p> <p>16 Could you repeat that?</p> <p>17 BY MR. TISI:</p> <p>18 Q. You knew when you drafted</p> <p>19 the papers that they were going to be</p> <p>20 going to the law firm for review and</p> <p>21 comment, didn't you?</p> <p>22 MR. HUDSON: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: I didn't draft</p>	<p style="text-align: right;">Page 245</p> <p>1 A. Yes.</p> <p>2 Q. And you know that in fact</p> <p>3 did happen, don't you?</p> <p>4 MR. HUDSON: Objection to</p> <p>5 form. Asked and answered.</p> <p>6 THE WITNESS: Okay. So no.</p> <p>7 BY MR. TISI:</p> <p>8 Q. Okay. Let's see if we can</p> <p>9 prove it to you.</p> <p>10 A. Okay.</p> <p>11 (Document marked for</p> <p>12 identification as Exhibit</p> <p>13 Muscat-20.)</p> <p>14 BY MR. TISI:</p> <p>15 Q. This is Number 20, Exhibit</p> <p>16 Number 20. Exhibit Number 20 is a</p> <p>17 document dated July 27th, 2005. Do you</p> <p>18 see that?</p> <p>19 A. Yes, I see that.</p> <p>20 Q. And that is a document under</p> <p>21 Crowell &amp; Moring, do you see that? It</p> <p>22 says it's from Robert Glenn, and he has a</p> <p>23 Crowell e-mail address, correct?</p> <p>24 A. Yes.</p>



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<p style="text-align: right;">Page 246</p> <p>1 Q. To Ralph Godell, who is 2 Luzenac North America, I'll represent to 3 you, correct? 4 A. Mm-hmm. 5 Q. And Steve Mann, who we 6 talked about is with J&amp;J, correct? 7 A. That's correct. 8 Q. Cc'd Ridgway Hall, who is 9 the lawyer for the law firm, the senior 10 partner, correct? 11 A. Yes. 12 Q. "Task deliverables from 13 Drs. Huncharek and Muscat." 14 Do you see that? 15 A. Yes. 16 Q. And did you ever consider 17 your two papers to be deliverables under 18 a contract? 19 MR. HUDSON: Objection to 20 form. 21 THE WITNESS: I'm sorry, I 22 don't think I understood the 23 question. 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 248</p> <p>1 document entitled "Ovarian Cancer: A 2 Critical Review." 3 Do you see that? 4 MR. HUDSON: Objection to 5 form. 6 THE WITNESS: Yes. 7 BY MR. TISI: 8 Q. And, now, that's the exact 9 title of the article that was ultimately 10 published by you in 2008, correct? 11 MR. HEGARTY: Objection to 12 form. 13 THE WITNESS: Is it the 14 exact title? It could be. I'd 15 have to look at it again. 16 BY MR. TISI: 17 Q. Well, let's see if we can 18 look at it together. 19 A. Okay. 20 Q. Okay. It says, "Perineal 21 Talc Use and Ovarian Cancer: A Critical 22 Review." 23 Do you see that? 24 A. Yes.</p>
<p style="text-align: right;">Page 247</p> <p>1 Q. I'm just looking at the 2 subject matter of the e-mail. It says, 3 "Task deliverables from Drs. Huncharek 4 and Muscat." 5 That's you, Dr. Muscat, 6 right? 7 A. Yes. 8 Q. Right. It says -- and we go 9 down below. It says, "We recently 10 received comments from Drs. Huncharek and 11 Muscat in response to our agreement 12 providing for comments to the NTP 13 regarding talc and ovarian cancer and for 14 conducting a meta-analysis of talc usage 15 in contraceptive diaphragms and ovarian 16 cancer. Do you see that? 17 A. Yes. 18 Q. And he provides five 19 documents. 20 Do you see that? 21 A. Yes. 22 Q. One is an executive summary, 23 two is a clean copy of -- and three is a 24 copy with Hall and Glenn's review of a</p>	<p style="text-align: right;">Page 249</p> <p>1 Q. Okay. Other than the word 2 "use," it's the exact same title, is it 3 not? 4 MR. HUDSON: Objection to 5 form. 6 MR. SILVER: Objection to 7 form. 8 BY MR. TISI: 9 Q. "Talc and Ovarian Cancer: A 10 Critical Review." The name of the 11 article is "Perineal Talc Use and Ovarian 12 Cancer: A Critical Review." 13 Do you see that? 14 A. Yes, I see it. 15 Q. Okay. And in fact, if you 16 look at it, this, what was attached to 17 this document that you drafted in 2005 18 ultimately became the article that was 19 published in the peer-reviewed 20 literature, and in fact this article 21 acknowledges Crowell &amp; Moring, does it 22 not? 23 MR. HUDSON: Objection to 24 form.</p>

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<p style="text-align: right;">Page 250</p> <p>1 MR. HEGARTY: Objection to 2 form. Asked and answered. 3 THE WITNESS: It does not. 4 It's a different document. It 5 does acknowledge Crowell &amp; Moring. 6 It's a different document. 7 BY MR. TISI: 8 Q. It's a different document 9 because the words were changed by Dr. -- 10 there were red lines and edits to what 11 you submitted, correct? 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: I'm sorry. 15 BY MR. TISI: 16 Q. Let me ask you this 17 question. Let me rephrase the question. 18 When you submitted a 19 document to -- first of all, you and 20 Dr. Huncharek did draft a document for 21 the lawyers entitled "Talc and Ovarian 22 Cancer: A Critical Review," correct? 23 MR. HUDSON: Objection to 24 form.</p>	<p style="text-align: right;">Page 252</p> <p>1 A. The paper that was 2 published, I wrote that. 3 Q. You wrote that? 4 A. Yeah. 5 Q. Did you have the documents 6 that Dr. Huncharek wrote in front of you 7 when you wrote this article? 8 MR. HEGARTY: Objection to 9 form. 10 BY MR. TISI: 11 Q. That appeared in 2008? 12 A. The documents that I used 13 were the ones that were referenced -- 14 Q. No. 15 A. -- in the article. 16 Q. No, when I asked you -- when 17 I asked you -- I asked you -- 18 A. Yes. 19 Q. -- when you looked at this 20 document, did you have in front of you 21 the -- what Dr. Huncharek had submitted 22 to Crowell &amp; Moring and what Crowell &amp; 23 Moring had returned back that was a red 24 line?</p>
<p style="text-align: right;">Page 251</p> <p>1 BY MR. TISI: 2 Q. You did? 3 A. Dr. Huncharek had submitted 4 that. 5 Q. Right. 6 A. Right. 7 Q. But you knew that it was 8 going to happen, right? 9 A. I assumed so, yes. 10 Q. Okay. When it came back, it 11 was different than when you wrote it, 12 correct? 13 A. I didn't write it. And I 14 don't have any knowledge of how it's 15 different. I understand that there was 16 some comments made. That's correct. 17 Q. Right. And the comments 18 made, when you say you didn't write it? 19 A. Yes. 20 Q. You didn't write this, you 21 didn't write this paper at all? 22 A. That's correct. 23 Q. Did you write the actual -- 24 the paper that was actually published?</p>	<p style="text-align: right;">Page 253</p> <p>1 MR. HEGARTY: Objection to 2 form. 3 THE WITNESS: I -- I don't 4 -- I don't recall of any red line. 5 I did have -- I think I had 6 a final copy of the paper that was 7 submitted -- 8 BY MR. TISI: 9 Q. Right. 10 A. -- to Crowell &amp; Moring. 11 And I subsequently wrote a 12 separate document which was published. 13 Q. In which you thanked Crowell 14 &amp; Moring, Inc.? 15 A. Yes, that's correct. 16 Q. And the reason why you 17 thanked Crowell &amp; Moring Inc. was because 18 the information that you wrote about was 19 derived from the paper that ultimately 20 came out of the contract, right? 21 MR. HUDSON: Objection to 22 form. 23 THE WITNESS: No. It was a 24 separate document.</p>



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<p>1 BY MR. TISI: 2 Q. Doctor, I understand that 3 this document is physically separate from 4 this document. 5 A. Mm-hmm-hmm. 6 Q. I'm asking you, then why did 7 you -- okay. 8 Why did you thank Crowell &amp; 9 Moring? 10 A. For the purposes of 11 disclosure and transparency. 12 Q. Why were you disclosing 13 Crowell &amp; Moring, Inc.? 14 A. To me it was like a -- it 15 was an overdisclosure. 16 Q. Okay. You are 17 overdisclosing because this article came 18 out of the process that was involved in 19 the contract? 20 A. We were -- I was 21 overdisclosing because the authors had 22 previously done work for Crowell &amp; 23 Moring. That's correct. 24 Q. The next article -- the next</p>	<p>1 form. 2 THE WITNESS: I believe so. 3 BY MR. TISI: 4 Q. Yeah. And Crowell &amp; Moring 5 and -- but you don't know what -- you 6 don't know what edits they had to that, 7 do you? 8 A. No. 9 Q. Now, if you go to the second 10 page of this e-mail, Exhibit 20. It 11 says, "Ridge and I have prepared red line 12 comments using track changes tool on the 13 comments to the NTP." 14 Do you see that? 15 A. Yes. 16 Q. That's The Critical Review 17 paper, correct? 18 A. Yes. 19 Q. "Using track changes on a 20 different font, please send us additional 21 comments or changes you wish for the 22 authors to consider in revising the NTP 23 document or the manuscript which will be 24 submitted to the medical literature."</p>
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<p>1 article referenced in Exhibit Number -- 2 MR. TISI: This is 20. 3 BY MR. TISI: 4 Q. This is 20. Is a manuscript 5 entitled "Use of Cosmetic Talc in 6 Contraceptive Diaphragms and Risk of 7 Ovarian Cancer: A Meta-Analysis of Nine 8 Observational Studies," correct? 9 A. I'm sorry. Which -- 10 Q. Look at the front of your -- 11 that document right there. 12 A. Okay. 13 Q. Number five it says a 14 manuscript. 15 A. Yes. 16 Q. And you submitted the 17 manuscript of what ultimately became 18 your -- 19 A. That manuscript was 20 submitted for publication. 21 Q. Right. And that was also 22 subject to review by Crowell &amp; Moring 23 correct? 24 MR. HEGARTY: Objection to</p>	<p>1 Correct? 2 A. Yes. 3 Q. Okay. And that's what it 4 says? I read that correctly? 5 A. Yes. 6 Q. Okay. And so it was your 7 understanding at this time that these 8 documents would be submitted to the 9 medical literature? 10 MR. HEGARTY: Objection to 11 form. 12 THE WITNESS: It wasn't my 13 understanding of anything. The -- 14 the two -- we call it the white 15 papers that were submitted to 16 Crowell &amp; Moring, was written on 17 behalf -- was written by 18 Dr. Huncharek. And those are the 19 events that happened. 20 BY MR. TISI: 21 Q. Right. You understood that 22 they would be subject to publication, 23 just as it indicates here in the 24 document, correct?</p>

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<p style="text-align: right;">Page 258</p> <p>1 MR. HUDSON: Objection to 2 form. 3 THE WITNESS: So the 4 meta-analysis was something that 5 was intended for publication. 6 BY MR. TISI: 7 Q. Right. And the other one 8 was actually used by you in actually 9 drafting what was the 2008 -- 10 MR. HEGARTY: Objection to 11 form. 12 BY MR. TISI: 13 Q. If I took the 2000 -- if I 14 looked at the manuscript here, and I 15 looked at the 2008 -- 16 A. Yes. 17 Q. -- there would be a lot of 18 overlap in language, wouldn't there be? 19 A. No, I don't think so. 20 Q. You don't think so? 21 A. No. 22 Q. It also says that, "You will 23 note that we recommended" -- now there is 24 a section on your 2008 study on</p>	<p style="text-align: right;">Page 260</p> <p>1 MR. SILVER: Objection to 2 form. 3 THE WITNESS: No. 4 BY MR. TISI: 5 Q. What qualifies you or 6 Dr. Huncharek to write about the 7 mineralogy of talc? 8 MR. HUDSON: Objection to 9 form. 10 THE WITNESS: Well, anybody 11 can write about it, right? I 12 mean, honestly what qualifies -- 13 it's a review article. So a 14 review article may entail review 15 of literature outside of 16 epidemiology. I don't think you 17 necessarily have to be an expert 18 on it. But if you want to write 19 about it, then that's your option. 20 BY MR. TISI: 21 Q. And you were clearly not an 22 expert on mineralogy, right? 23 A. I wouldn't call myself an 24 expert. But if I know enough to read</p>
<p style="text-align: right;">Page 259</p> <p>1 mineralogy of talc, correct? 2 A. Yes. 3 Q. All right. It says, "You 4 will note that the recommended section 5 related to talc mineralogy and its 6 similarity to asbestos, needs attention 7 by Rich Zazenski or a mineralogist." 8 Do you see that in this? 9 A. I see that. 10 Q. Do you know whether or not a 11 mineralogist -- first of all, let's be 12 clear. Neither you or Dr. Huncharek are 13 mineralogists, correct? 14 A. That's correct. 15 Q. Okay. And there's a whole 16 section in the 2008 paper on mineralogy, 17 correct? 18 A. Yes. 19 Q. Do you know whether or not 20 Dr. Huncharek got a consultation from 21 anybody at Imerys about the section on 22 mineralogy related to talc? 23 MR. HUDSON: Objection to 24 form.</p>	<p style="text-align: right;">Page 261</p> <p>1 something about it and write about it -- 2 Q. Okay. 3 A. -- that may be relevant to 4 an article. 5 Q. So if I know enough about, 6 like, making spaghetti sauce, I could be 7 a chef in Rome, right? 8 MR. SILVER: Objection to 9 form. Move to strike. 10 THE WITNESS: Uh -- 11 BY MR. TISI: 12 Q. My point is, Doctor -- 13 A. Let me make a point, okay, 14 because I -- so I hope this explains 15 things. 16 Is that as scientists, and 17 particularly someone like myself that 18 reviews articles for the peer-reviewed 19 literature that actually serves on NIH 20 study sections, it's very common that I 21 review things that are outside my 22 particular topic area. I have to know 23 them. I can't become an expert in that. 24 But it's expected that I have some</p>

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<p style="text-align: right;">Page 262</p> <p>1 working knowledge of it. 2 So a lot of scientific 3 communication, is written by -- includes 4 things where you're not necessarily, 5 you're an expert on it. But it may be 6 included in the report, because it's 7 relevant to the report. You don't have 8 to be an expert. 9 Okay. There's a risk to 10 that. Maybe you wrote something that's 11 incorrect. But that's just part of the 12 scientific process. 13 Q. Well, did you get a consult 14 from a mineralogist? Because one of the 15 things that you write -- and I'm going to 16 back up here. I'm a little bit off 17 topic, but I'll do it any way. One of 18 the things in every one of your articles 19 that you wrote on this topic, is you have 20 a section where you talk about asbestos, 21 and that asbestos was a problem in the 22 1970s, but since the 1970s, it's no 23 longer a problem. 24 MR. HUDSON: Objection to</p>	<p style="text-align: right;">Page 264</p> <p>1 explained by the fact that there was some 2 suggestion in the medical literature that 3 there was talc contamination in the 4 1970s, but that was no longer the case. 5 Does that sound familiar to you? 6 MR. HUDSON: Objection to 7 form. 8 THE WITNESS: So that's -- 9 that's not entirely correct. 10 BY MR. TISI: 11 Q. Okay. Well, what is 12 correct? 13 MR. HEGARTY: Objection to 14 form. 15 THE WITNESS: I may have 16 written the fact in some of the 17 other articles that were 18 published, that there may be a 19 confusion between asbestos and 20 talc. 21 But I'd have to go back and 22 look at all my stuff to see 23 specifically what you're referring 24 to.</p>
<p style="text-align: right;">Page 263</p> <p>1 form. 2 BY MR. TISI: 3 Q. Generally speaking? 4 MR. HUDSON: Objection to 5 form. There's no question 6 pending. 7 BY MR. TISI: 8 Q. Correct? 9 A. Okay. 10 Q. That's a theme that appears 11 in all of your -- in your articles on 12 talc? 13 MR. HEGARTY: Objection. 14 THE WITNESS: I'd have to go 15 back and look at it. Okay. 16 BY MR. TISI: 17 Q. Generally, and we'll go 18 through this. 19 A. Okay. 20 Q. But generally speaking, your 21 position has been, and you have 22 written -- you wrote to the FDA, you 23 wrote to -- in your articles, that some 24 of the epidemiology on talc might be</p>	<p style="text-align: right;">Page 265</p> <p>1 BY MR. TISI: 2 Q. But you actually also make a 3 different point, which is after the 4 1970s, asbestos was not a problem in 5 talc. Do you remember making that 6 assertion? 7 MR. HUDSON: Objection to 8 form. 9 THE WITNESS: I'd have to 10 look at the specific paper. 11 BY MR. TISI: 12 Q. Okay. Let me ask you this. 13 Because I'll be -- I'm going to get into 14 this a little bit later. 15 A. Okay, okay. 16 Q. But you have never done, if 17 that statement appears in your medical 18 literature -- and I'm going to tell you 19 that it appears over and over and over 20 again, that as of the 1970s, the company 21 has tested for talc -- has tested the 22 talc for asbestos, and there's no 23 contamination. 24 A. Yes.</p>



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<p>1 Q. You never cited, and I'm</p> <p>2 going to tell you, you never cited a</p> <p>3 single study or survey or anything like</p> <p>4 that.</p> <p>5 Did you ever get that from</p> <p>6 anybody?</p> <p>7 MR. HUDSON: Objection to</p> <p>8 form.</p> <p>9 MR. SILVER: Objection to</p> <p>10 form.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Did anybody ever tell you</p> <p>13 that?</p> <p>14 MR. HUDSON: Same objection.</p> <p>15 THE WITNESS: So I was on</p> <p>16 the IARC meeting, okay. I was on</p> <p>17 the panel. I'm sorry I wasn't on</p> <p>18 the panel. But I attended the</p> <p>19 panel meetings.</p> <p>20 I've read the IARC</p> <p>21 monograph. And that's something</p> <p>22 that has been in the literature,</p> <p>23 so that it's thought that based on</p> <p>24 IARC that the talc has been</p>	<p>1 something that is specific to a</p> <p>2 particular data element, I'm not</p> <p>3 sure that I would cite something.</p> <p>4 But I can't say why did I</p> <p>5 cite this or not cite this.</p> <p>6 There's always reasons for</p> <p>7 citations. So I'm not sure what</p> <p>8 the point is though, to be honest.</p> <p>9 MR. HUDSON: Counsel, we've</p> <p>10 been going about another hour and</p> <p>11 a half or so. I don't know what</p> <p>12 your lunch plans are, but you may</p> <p>13 want to consider --</p> <p>14 MR. TISI: I Want to just</p> <p>15 get through this. If you mind,</p> <p>16 just give me a little leeway for</p> <p>17 the next 20 minutes, I'll be done</p> <p>18 with this.</p> <p>19 MR. HUDSON: That's fair. I</p> <p>20 just wanted to make that request.</p> <p>21 BY MR. TISI:</p> <p>22 Q. Okay. Can you go to the</p> <p>23 privilege log. We were talking about</p> <p>24 Crowell &amp; Moring. Can I go back to this</p>
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<p>1 asbestos-free.</p> <p>2 So those are -- those are</p> <p>3 the basis of -- those are one of</p> <p>4 the basis. I can't say it's all</p> <p>5 of it, but --</p> <p>6 BY MR. TISI:</p> <p>7 Q. You never cited in your</p> <p>8 medical literature a single -- you didn't</p> <p>9 cite IARC. You cited nothing for that</p> <p>10 proposition, in your articles.</p> <p>11 Can you point to me one</p> <p>12 survey, one article, one anything in the</p> <p>13 medical literature that indicates that</p> <p>14 talc was asbestos-free since the 1970s?</p> <p>15 MR. HUDSON: Objection to</p> <p>16 form.</p> <p>17 MR. HEGARTY: Objection to</p> <p>18 form.</p> <p>19 THE WITNESS: So I'm not</p> <p>20 sure -- I'm not sure why I would</p> <p>21 be -- I'd have to look at it to</p> <p>22 try and understand, is there a</p> <p>23 need for this citation. Okay.</p> <p>24 Because unless it's</p>	<p>1 chart right here.</p> <p>2 We were talking about, so</p> <p>3 your relationship with Crowell &amp; Moring</p> <p>4 began in about 2005. And move forward,</p> <p>5 right, you continued to meet with Bob</p> <p>6 Glenn or speak with Bob Glenn throughout</p> <p>7 the 2000s, correct?</p> <p>8 A. No.</p> <p>9 Q. No, you have not?</p> <p>10 A. No.</p> <p>11 Q. Do you know whether</p> <p>12 Dr. Huncharek did?</p> <p>13 A. No.</p> <p>14 Q. Okay. But you continued --</p> <p>15 okay. Let's put a block here in the 2000</p> <p>16 time frame.</p> <p>17 2005 you were involved with</p> <p>18 the IARC for the mining company, correct?</p> <p>19 MR. HEGARTY: Objection to</p> <p>20 form.</p> <p>21 MR. HUDSON: Objection to</p> <p>22 form.</p> <p>23 BY MR. TISI:</p> <p>24 Q. IMA North America?</p>



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<p style="text-align: right;">Page 270</p> <p>1 A. I was an industry observer.  2 Q. Okay. You did work in 2000  3 for the NTP for PCPC and in 2009 for the  4 Citizen's Petition, correct?  5 MR. HEGARTY: Objection to  6 form.  7 THE WITNESS: I did not do  8 work for the NTP. I did work for  9 The Weinberg Group.  10 BY MR. TISI:  11 Q. Who also and the paper was  12 submitted by --  13 A. Submitted to NTP.  14 Q. By PCPC?  15 A. Yes.  16 Q. And in 2005 going forward  17 you had various meetings with Imerys,  18 including being in a contract with them  19 through Crowell &amp; Moring, proposing  20 studies, meeting in Skillman, being  21 involved in the Citizen's Petition,  22 correct?  23 MR. HEGARTY: Objection to  24 form.</p>	<p style="text-align: right;">Page 272</p> <p>1 Q. Now, first of all,  2 actually -- where's my -- you have in  3 front of you the privilege log. But I  4 pulled from the privilege log  5 communications with Crowell &amp; Moring.  6 I'm going to mark all these slides by the  7 way. I'm going to mark this one in  8 particular.  9 A. Okay.  10 MR. TISI: As -- what  11 exhibit are we up to?  12 (Document marked for  13 identification as Exhibit  14 Muscat-21.)  15 BY MR. TISI:  16 Q. This is 21.  17 MR. TISI: And I'll give  18 copies to everybody, but these are  19 pulled from the privilege log.  20 BY MR. TISI:  21 Q. And you see communications  22 with the lawyers, Crowell &amp; Moring,  23 starting in 2005.  24 Do you see that?</p>
<p style="text-align: right;">Page 271</p> <p>1 MR. HUDSON: Objection to  2 form.  3 MR. SILVER: Objection to  4 form.  5 THE WITNESS: So as I  6 mentioned with regard to the  7 meeting at J&amp;J, I didn't know  8 there was any Imerys  9 representative there.  10 BY MR. TISI:  11 Q. Okay. Other than that, that  12 was correct, what I just said, right?  13 MR. HUDSON: Objection to  14 form.  15 MR. SILVER: Objection to  16 form.  17 THE WITNESS: You'd have to  18 repeat it, because it was a lot of  19 stuff.  20 BY MR. TISI:  21 Q. Let's move on.  22 The last column here is  23 Shook Hardy &amp; Bacon?  24 A. Yes.</p>	<p style="text-align: right;">Page 273</p> <p>1 MR. HEGARTY: Did you say  2 that you're marking this as an  3 exhibit?  4 MR. TISI: I will.  5 MR. HEGARTY: Okay. Sorry.  6 BY MR. TISI:  7 Q. Do you see that?  8 A. I'm sorry, which one?  9 Q. 2005. You see there's a  10 date for the documents that are being  11 withheld?  12 A. Yes.  13 Q. Okay. 2005.  14 A. Yes.  15 Q. February -- excuse me,  16 correct.  17 And then it goes through  18 2006. Do you see that?  19 A. Yes.  20 Q. Were you communicating back  21 and forth with the lawyers at Crowell &amp;  22 Moring between 2005 and 2006?  23 A. No.  24 Q. You were not?</p>



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<p>1 A. No.</p> <p>2 Q. And --</p> <p>3 A. Not that I remember, no.</p> <p>4 Q. And there was no</p> <p>5 consultation for legal advice or anything</p> <p>6 like that --</p> <p>7 A. No.</p> <p>8 Q. -- in that time frame?</p> <p>9 A. No.</p> <p>10 MR. TISI: Counsel, I would</p> <p>11 make -- based upon the testimony,</p> <p>12 I'd like to make a request for</p> <p>13 those documents that were withheld</p> <p>14 on that basis.</p> <p>15 MR. SILVER: It's denied,</p> <p>16 but you can go forward.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Next one is Shook Hardy &amp;</p> <p>19 Bacon. Let's talk about Shook Hardy &amp;</p> <p>20 Bacon a bit.</p> <p>21 MR. HEGARTY: Are you going</p> <p>22 to mark that as an exhibit?</p> <p>23 MR. TISI: I will mark that</p> <p>24 as an exhibit. This is 21.</p>	<p>1 BY MR. TISI:</p> <p>2 Q. Now, you said you became an</p> <p>3 expert consultant with them in 2010?</p> <p>4 A. Yes.</p> <p>5 Q. And in fact, you have been</p> <p>6 identified as an expert in litigation on</p> <p>7 behalf of Shook Hardy &amp; Bacon, correct?</p> <p>8 A. That's correct.</p> <p>9 Q. You were paid for that?</p> <p>10 A. Yes.</p> <p>11 Q. When did that relationship</p> <p>12 start?</p> <p>13 A. Well, approximately 2010.</p> <p>14 Q. So it would have started</p> <p>15 before your 2011 article that wasn't</p> <p>16 listed on your CV was submitted for peer</p> <p>17 review?</p> <p>18 MR. HEGARTY: Objection to</p> <p>19 form.</p> <p>20 MR. HUDSON: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: I don't know</p> <p>23 when that was submitted.</p> <p>24 BY MR. TISI:</p>
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<p>1 BY MR. TISI:</p> <p>2 Q. Now just to remind the jury</p> <p>3 and the judge, Shook Hardy &amp; Bacon are</p> <p>4 the lawyers -- Mr. Hegarty is sitting</p> <p>5 here. Kat Frazier is a lawyer for Shook</p> <p>6 Hardy &amp; Bacon. Did you ever meet Gene</p> <p>7 Williams? Do you know who Gene Williams</p> <p>8 is?</p> <p>9 A. Yes.</p> <p>10 Q. They're the lawyers</p> <p>11 representing Johnson &amp; Johnson for claims</p> <p>12 brought by women who claim that talc</p> <p>13 caused ovarian cancer.</p> <p>14 A. Yes.</p> <p>15 Q. And you know that, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Now, I pulled -- they're</p> <p>18 not, to your knowledge, Shook Hardy &amp;</p> <p>19 Bacon in the business of doing scientific</p> <p>20 research, are they?</p> <p>21 MR. HUDSON: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: I'm unaware of</p> <p>24 that.</p>	<p>1 Q. It was submitted in April of</p> <p>2 2011.</p> <p>3 A. Okay.</p> <p>4 Q. If that were true, you were</p> <p>5 already working as a consultant, an</p> <p>6 expert, for Shook Hardy &amp; Bacon, true?</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: I don't know.</p> <p>10 Perhaps.</p> <p>11 BY MR. TISI:</p> <p>12 Q. That wasn't disclosed on</p> <p>13 that article, was it?</p> <p>14 A. I didn't write the article.</p> <p>15 Q. It went in under your name,</p> <p>16 sir, did it?</p> <p>17 A. Yes.</p> <p>18 Q. And you're also were aware</p> <p>19 Dr. Huncharek was retained as an expert</p> <p>20 by Shook Hardy &amp; Bacon as well?</p> <p>21 A. That's correct.</p> <p>22 Q. And he didn't disclose --</p> <p>23 you were retained at about the same time,</p> <p>24 true?</p>

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<p style="text-align: right;">Page 278</p> <p>1 A. That's right.</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 BY MR. TISI:</p> <p>5 Q. And they weren't -- he</p> <p>6 wasn't disclosed as an expert in</p> <p>7 litigation in that article either,</p> <p>8 correct?</p> <p>9 MR. HUDSON: Objection to</p> <p>10 form.</p> <p>11 MR. HEGARTY: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: I don't have</p> <p>14 it in front of me. I assume so.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Okay. We'll talk about</p> <p>17 that.</p> <p>18 A. Okay.</p> <p>19 Q. But I have pulled from the</p> <p>20 privilege log as I did with the other --</p> <p>21 I'll have this marked but I'll --</p> <p>22 MR. TISI: Here is a copy,</p> <p>23 counsel.</p> <p>24 MR. HUDSON: Thank you.</p>	<p style="text-align: right;">Page 280</p> <p>1 A. Yes, I do.</p> <p>2 Q. That was about the time that</p> <p>3 you were writing your report for the NTP</p> <p>4 wasn't it?</p> <p>5 A. Yes.</p> <p>6 Q. 12/7, 2004. Do you see</p> <p>7 that?</p> <p>8 A. Yes.</p> <p>9 Q. That's about the time that</p> <p>10 you were being retained by Crowell &amp;</p> <p>11 Moring to work for -- on these two</p> <p>12 articles, correct?</p> <p>13 A. Yes.</p> <p>14 Q. 6/21/2007, do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. That's about the time</p> <p>17 that you were submitting your diaphragm</p> <p>18 study for publication, correct?</p> <p>19 A. Yes.</p> <p>20 Q. And if you look over to the</p> <p>21 right, the privilege description says,</p> <p>22 "Materials provided by counsel in</p> <p>23 connection with ongoing litigation."</p> <p>24 Do you see that?</p>
<p style="text-align: right;">Page 279</p> <p>1 (Document marked for</p> <p>2 identification as Exhibit</p> <p>3 Muscat-23.)</p> <p>4 MR. TISI: This is 23. Do</p> <p>5 you have a sticker for this? Can</p> <p>6 you put 23 on there. Thanks.</p> <p>7 BY MR. TISI:</p> <p>8 Q. I sorted it by date. The</p> <p>9 privileges relating to Dr. -- to Shook</p> <p>10 Hardy &amp; Bacon.</p> <p>11 MR. HUDSON: Do you have an</p> <p>12 extra copy?</p> <p>13 MR. TISI: I have what you</p> <p>14 have. I can get you at a break.</p> <p>15 But it's too messy over here for</p> <p>16 me to get it.</p> <p>17 BY MR. TISI:</p> <p>18 Q. The date of the documents,</p> <p>19 at least that's my understanding, are</p> <p>20 sorted on the fourth column over. Do you</p> <p>21 see that?</p> <p>22 A. Yes, I do.</p> <p>23 Q. See a document, dated</p> <p>24 October 17th, 2000.</p>	<p style="text-align: right;">Page 281</p> <p>1 A. Yes, I do.</p> <p>2 Q. And that's listed every --</p> <p>3 all the way down, correct?</p> <p>4 A. Mm-hmm.</p> <p>5 Q. 10/14/2008, do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. That's about the time that</p> <p>8 you were submitting your critical review</p> <p>9 analysis to be published, correct?</p> <p>10 A. Mm-hmm. That's correct.</p> <p>11 Q. 10/7/2010, do you see that?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. That's about the time</p> <p>14 that you were preparing Exhibit Number --</p> <p>15 the 2011 paper on the epidemiology of</p> <p>16 talc, correct?</p> <p>17 MR. HEGARTY: Objection to</p> <p>18 form.</p> <p>19 MR. HUDSON: Objection to</p> <p>20 form.</p> <p>21 THE WITNESS: I'm sorry, can</p> <p>22 you repeat that, please?</p> <p>23 BY MR. TISI:</p> <p>24 Q. That's about the time that</p>

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<p style="text-align: right;">Page 282</p> <p>1 you were -- that the paper that was the 2 2011 paper that's not listed on your CV, 3 was actually being drafted for 4 publication, correct? 5 A. Yes. 6 MR. HEGARTY: Objection to 7 form. 8 BY MR. TISI: 9 Q. If you can continue to go 10 down, all the way through March and 11 April, that was before your 2011 12 publication, correct? 13 MR. HEGARTY: Objection to 14 form. 15 THE WITNESS: I don't 16 remember the dates of that, so the 17 exact date of that. But yes. 18 MR. TISI: Could you bring 19 up document 007, please. 20 BY MR. TISI: 21 Q. I'm putting up -- 22 MR. TISI: I'm going to have 23 this marked as Exhibit Number 24. 24 (Document marked for</p>	<p style="text-align: right;">Page 284</p> <p>1 a litigation expert, true? 2 A. I was retained in 2010. 3 Q. Correct. And so at the time 4 that this article was published, you were 5 already an expert in litigation being 6 paid by the lawyers for J&amp;J, correct? 7 MR. HUDSON: Objection to 8 form. 9 THE WITNESS: I was a Shook 10 Hardy &amp; Bacon -- I was working for 11 Shook Hardy &amp; Bacon, that is 12 correct. 13 BY MR. TISI: 14 Q. That's right? 15 A. Right. 16 Q. Did you disclose that by the 17 way in your acknowledgment? 18 A. So I didn't write this 19 paper. I wasn't responsible for the 20 acknowledgment. 21 Q. Was -- Dr. Huncharek was 22 also -- you mentioned that he was also an 23 expert. 24 A. Yes, that's correct.</p>
<p style="text-align: right;">Page 283</p> <p>1 identification as Exhibit 2 Muscat-24.) 3 BY MR. TISI: 4 Q. This is 24. This is 5 actually in your binder, sir. 6 A. Okay. 7 Q. This is your 2011 paper. 8 MR. SILVER: What exhibit is 9 it? 10 MR. TISI: 24. 11 BY MR. TISI: 12 Q. This is your 2011 paper, 13 sir? 14 A. Yes. 15 Q. It was received on 16 March 31st, 2011? 17 A. Yes. 18 Q. You had a lot of contact 19 with Shook Hardy &amp; Bacon before 2011, 20 correct? 21 MR. HUDSON: Objection to 22 form. 23 BY MR. TISI: 24 Q. You were already retained as</p>	<p style="text-align: right;">Page 285</p> <p>1 Q. Did this acknowledgment -- 2 you were aware that this was going to be 3 published. This wasn't, like, a surprise 4 to you, was it? 5 A. Yes. 6 Q. Did you ever say to 7 Dr. Muscat, gee -- to Dr. Huncharek, 8 "Gee, I think, we're already litigation 9 experts now. We've done a lot of work 10 for these companies. We should disclose 11 that in the medical literature"? 12 MR. HUDSON: Objection to 13 form. 14 THE WITNESS: So it was 15 disclosed. All right. If you 16 look at the acknowledgment, 17 Dr. Muscat -- Huncharek and Muscat 18 were consultants at Johnson &amp; 19 Johnson Consumer Product Worldwide 20 at the time of the initial drafts 21 of this manuscript were produced. 22 BY MR. TISI: 23 Q. It doesn't say that you were 24 a current litigation expert defending</p>



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<p style="text-align: right;">Page 286</p> <p>1 product liability suits, does it?</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 THE WITNESS: It doesn't say</p> <p>5 those words. But it says they</p> <p>6 were consultants to Johnson.</p> <p>7 That's the disclosure.</p> <p>8 BY MR. TISI:</p> <p>9 Q. Does it tell the reader that</p> <p>10 you were actually a paid litigation</p> <p>11 expert? There's a difference between --</p> <p>12 between disclosing being a consultant in</p> <p>13 the normal course of business and being a</p> <p>14 litigation consultant, correct?</p> <p>15 MR. SILVER: Objection.</p> <p>16 Argumentive.</p> <p>17 MR. HUDSON: Objection to</p> <p>18 form.</p> <p>19 THE WITNESS: I don't know.</p> <p>20 All I can say is that, Huncharek</p> <p>21 did the disclosure. I think he</p> <p>22 did it properly. We were J&amp;J</p> <p>23 consultants. That's what being a</p> <p>24 litigation expert is.</p>	<p style="text-align: right;">Page 288</p> <p>1 prior to this article?</p> <p>2 MR. HUDSON: Objection to</p> <p>3 form.</p> <p>4 THE WITNESS: So, that</p> <p>5 wasn't my responsibility as first</p> <p>6 author.</p> <p>7 BY MR. TISI:</p> <p>8 Q. Well, but you both have to</p> <p>9 sign disclosures, don't you?</p> <p>10 A. Yeah. The disclosure was</p> <p>11 signed.</p> <p>12 Q. Okay. Did you both sign the</p> <p>13 disclosure?</p> <p>14 A. I assume I signed it. I</p> <p>15 don't remember exactly.</p> <p>16 Q. Okay. Do you have the</p> <p>17 documents? Because we haven't seen them?</p> <p>18 A. Okay. I don't know if I</p> <p>19 have the documents.</p> <p>20 Q. In fact, I've seen no</p> <p>21 disclosures other than for the 2008</p> <p>22 Critical Review paper. Do you have any</p> <p>23 peer review notes or disclosures for any</p> <p>24 of your articles that you wrote on behalf</p>
<p style="text-align: right;">Page 287</p> <p>1 I think the disclosure is</p> <p>2 fine.</p> <p>3 BY MR. TISI:</p> <p>4 Q. You do?</p> <p>5 A. Yeah, I do.</p> <p>6 Q. And you think anybody who is</p> <p>7 looking at this would know, you know,</p> <p>8 gee, this guy -- this guy is working</p> <p>9 being paid by the company to defend the</p> <p>10 company in lawsuits?</p> <p>11 MR. HUDSON: Objection to</p> <p>12 form.</p> <p>13 MR. SILVER: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: I can't</p> <p>16 comment to that. This is a</p> <p>17 proper -- this is a proper</p> <p>18 disclosure in my mind.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Did you tell -- did you tell</p> <p>21 the medical journal that you were an</p> <p>22 expert in litigation and that you had</p> <p>23 been consulting with Shook Hardy &amp; Bacon</p> <p>24 in connection with ongoing litigation</p>	<p style="text-align: right;">Page 289</p> <p>1 of the talc industry?</p> <p>2 MR. HUDSON: Objection to</p> <p>3 form.</p> <p>4 MR. HEGARTY: Objection to</p> <p>5 form.</p> <p>6 THE WITNESS: Which -- which</p> <p>7 paper are you referring to?</p> <p>8 BY MR. TISI:</p> <p>9 Q. Well, how about let's start</p> <p>10 with the diaphragm study that was funded</p> <p>11 by J&amp;J and Imerys.</p> <p>12 MR. SILVER: Objection.</p> <p>13 THE WITNESS: The</p> <p>14 meta-analysis?</p> <p>15 BY MR. TISI:</p> <p>16 Q. The meta-analysis.</p> <p>17 A. The published meta-analysis?</p> <p>18 Q. Yeah. Do you have the peer</p> <p>19 reviewed notes for that?</p> <p>20 A. The peer review notes?</p> <p>21 Q. The peer review comments by</p> <p>22 the peer reviewers.</p> <p>23 A. No.</p> <p>24 Q. Do you have the disclosure</p>



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<p style="text-align: right;">Page 290</p> <p>1 forms?</p> <p>2 A. No.</p> <p>3 Q. We're going to talk about</p> <p>4 this in a minute, but that's not the</p> <p>5 first journal that that article was sent</p> <p>6 to, was it?</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 MR. HUDSON: Objection to</p> <p>10 form.</p> <p>11 THE WITNESS: The 2003</p> <p>12 meta-analysis?</p> <p>13 BY MR. TISI:</p> <p>14 Q. The 2007 diaphragm study.</p> <p>15 It was rejected by papers before it was</p> <p>16 finally published in European Journal of</p> <p>17 Cancer Research?</p> <p>18 MR. HEGARTY: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: I don't</p> <p>21 remember the history of it. But</p> <p>22 right.</p> <p>23 BY MR. TISI:</p> <p>24 Q. It was -- it was rejected,</p>	<p style="text-align: right;">Page 292</p> <p>1 Q. But it was -- it was</p> <p>2 rejected by several journals before it</p> <p>3 was accepted for publication, correct?</p> <p>4 MR. HEGARTY: Objection to</p> <p>5 form.</p> <p>6 THE WITNESS: It was -- it</p> <p>7 was rejected by a couple of</p> <p>8 journals.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Right. And the last time it</p> <p>11 was they told you to take smoking as a</p> <p>12 confounder out, right?</p> <p>13 MR. HEGARTY: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: I don't know</p> <p>16 what you're referring to</p> <p>17 specifically.</p> <p>18 BY MR. TISI:</p> <p>19 Q. We'll talk about that.</p> <p>20 MR. TISI: This is probably</p> <p>21 a good time to stop.</p> <p>22 THE VIDEOGRAPHER: Going off</p> <p>23 the record at 1:18 p.m.</p> <p>24 (Lunch break.)</p>
<p style="text-align: right;">Page 291</p> <p>1 wasn't it?</p> <p>2 A. The meta-analysis.</p> <p>3 Q. Was rejected. The diaphragm</p> <p>4 was rejected before it was published?</p> <p>5 MR. HEGARTY: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: No, I don't --</p> <p>8 I don't have any recollection of</p> <p>9 that.</p> <p>10 BY MR. TISI:</p> <p>11 Q. And your Critical Review was</p> <p>12 rejected by no less than four journals</p> <p>13 before it was published, right?</p> <p>14 MR. HEGARTY: Objection to</p> <p>15 form.</p> <p>16 MR. HUDSON: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: That's</p> <p>19 incorrect. It was submitted, it</p> <p>20 was rejected. That's correct.</p> <p>21 BY MR. TISI:</p> <p>22 Q. By Lancet, JAMA -- we'll go</p> <p>23 through that later.</p> <p>24 A. Okay.</p>	<p style="text-align: right;">Page 293</p> <p>1 MR. TISI: 21 was the</p> <p>2 Crowell &amp; Moring excerpts slide.</p> <p>3 I think that is identified, and</p> <p>4 you have that as an exhibit</p> <p>5 already as 21.</p> <p>6 22 was, I think, skipped</p> <p>7 over by me. So I'm going to</p> <p>8 use -- 22 is the consulting</p> <p>9 ovarian cancer chart that I worked</p> <p>10 on with him.</p> <p>11 I'll give that to you.</p> <p>12 (Document marked for</p> <p>13 identification as Exhibit</p> <p>14 Muscat-22.)</p> <p>15 (Whereupon, a discussion is</p> <p>16 held off the record.)</p> <p>17 THE VIDEOGRAPHER: We are</p> <p>18 back on video record at 2:09 p.m.</p> <p>19 BY MR. TISI:</p> <p>20 Q. I went through your</p> <p>21 publications and your timelines before.</p> <p>22 A. Mm-hmm.</p> <p>23 Q. And the timeline of things</p> <p>24 that happened. I'm going to now talk a</p>



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<p>1 little bit about the funding of the 2 reports and publications that you did. 3 And I'm going to try to slow down a 4 little bit, because I know we got into a 5 pace before, and I want to slow down a 6 little bit? 7 A. Okay. 8 Q. Okay. Let's talk a little 9 bit about the process. Before we talk 10 about your actual articles, and I think 11 there were six articles and two -- seven 12 articles and two reports on the 13 publications list that we talked about. 14 Does that make sense to you? 15 A. Yes. 16 Q. Okay. Let's talk about 17 articles for a moment and publishing in 18 the peer-reviewed literature. 19 When an article is submitted 20 for publication, does -- do each of the 21 authors have to identify affiliations and 22 conflicts that might be considered by the 23 journal in assessing the financial and 24 professional bias of the authors?</p>	<p>1 important to have a background, 2 kind of the rules of disclosure 3 have changed over time. 4 So what they are today 5 certainly isn't what they are back 6 then -- or sorry, 15, 20 years 7 ago. 8 So it's changed. There 9 usually is some type of statement, 10 and it could vary from journal to 11 journal. 12 BY MR. TISI: 13 Q. But typically, is it 14 something that is standard that authors 15 must disclose potential conflicts that 16 they have, financial and otherwise? 17 A. I'd say it's common. Yes. 18 Q. Okay. Putting aside the 19 issue of potential bias issues, do they 20 also have to disclose anybody who makes a 21 substantive contribution to the article? 22 In other words, any contributors to the 23 paper? 24 MR. HEGARTY: Objection to</p>
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<p>1 MR. HUDSON: Objection to 2 form. 3 THE WITNESS: I'm sorry. 4 Can you repeat that, please? 5 BY MR. TISI: 6 Q. Yes. Must an author of a 7 peer-reviewed -- of an article, in order 8 to get the article accepted, have to 9 disclose potential conflicts? 10 A. So there's -- there's a form 11 that the journal may ask you to fill out. 12 And so depending upon what the journal 13 form is requesting, then you answer it. 14 Q. Okay. And the form 15 typically -- typically speaking, requires 16 authors of articles to actually disclose 17 any financial or other conflicts that 18 they might have with regard to the 19 subject matter in which they seek 20 publication? 21 MR. HUDSON: Objection to 22 form. 23 THE WITNESS: So just be 24 clear, because I think it's</p>	<p>1 form. 2 THE WITNESS: If someone 3 makes a substantive contribution 4 to the article, they would 5 probably be a co-author. 6 BY MR. TISI: 7 Q. They should be? 8 A. Most of the time, yeah. 9 Q. I mean, you can't have 10 articles that are essentially 11 ghostwritten by one person but go under 12 another person's name? 13 MR. HEGARTY: Objection to 14 form. 15 THE WITNESS: I'm not aware 16 of ghostwriting, no. 17 BY MR. TISI: 18 Q. Okay. In other words, if 19 somebody writes a section of an 20 article -- let's say there's three 21 sections of an article, and somebody 22 writes Section 1, somebody writes Section 23 2, and somebody writes Section 3, all 24 three -- the people who wrote each of</p>

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<p>1 those sections should be identified as</p> <p>2 authors?</p> <p>3 A. Not necessarily. You know,</p> <p>4 you may have a -- you just -- I don't</p> <p>5 mean to be picky here, but, like, for</p> <p>6 instance, if I have an administrative</p> <p>7 assistant pull up some references, and</p> <p>8 those references are added to the</p> <p>9 article, she would not be identified as</p> <p>10 an author.</p> <p>11 Q. Well, that's why I asked the</p> <p>12 question, if somebody writes Section 1,</p> <p>13 somebody writes Section 2, and somebody</p> <p>14 writes Section 3, or edits Section 1,</p> <p>15 edits Section 2, or edits Section 3,</p> <p>16 those people -- when I say -- when I mean</p> <p>17 editing, I don't mean editing a comma or</p> <p>18 a period. I mean editing. Those people</p> <p>19 should be identified as contributors to</p> <p>20 the article?</p> <p>21 MR. HEGARTY: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: In a</p> <p>24 peer-reviewed article?</p>	<p>1 BY MR. TISI:</p> <p>2 Q. Well, in order to accept it</p> <p>3 for publication, they want to know the</p> <p>4 people -- who is actually writing the</p> <p>5 article?</p> <p>6 A. So sometimes, just to be</p> <p>7 clear, not all the time, but sometimes,</p> <p>8 some journals ask to identify the author</p> <p>9 contribution. So there are authors who</p> <p>10 may not necessarily be writing it. They</p> <p>11 may have done the statistical analyses.</p> <p>12 So they would be acknowledged as having</p> <p>13 done the statistical analyses.</p> <p>14 Q. Okay. So -- okay. So now</p> <p>15 my question is -- to you is, you also</p> <p>16 have to certify that the work that was</p> <p>17 done in the article was the author's</p> <p>18 work?</p> <p>19 MR. HEGARTY: Objection to</p> <p>20 form.</p> <p>21 BY MR. TISI:</p> <p>22 Q. I mean, it's the flip side.</p> <p>23 Not only must you disclose who the</p> <p>24 authors were, but you also need to</p>
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<p>1 BY MR. TISI:</p> <p>2 Q. Yes, correct.</p> <p>3 A. I mean, generally, right, if</p> <p>4 you make a contribution, you'd be a</p> <p>5 co-author.</p> <p>6 Q. You should be?</p> <p>7 A. Most of the time. I'm sure</p> <p>8 there are -- you can probably think of</p> <p>9 circumstances, but in general, I think</p> <p>10 that's correct.</p> <p>11 Q. Right. Because people who</p> <p>12 read the articles are entitled to know</p> <p>13 who the contributors are?</p> <p>14 A. Yes.</p> <p>15 Q. When I say people who read</p> <p>16 the articles, I'm talking about not only</p> <p>17 the people who would actually read it as</p> <p>18 it's published, but also the editors of</p> <p>19 the journals?</p> <p>20 MR. HEGARTY: Objection to</p> <p>21 form.</p> <p>22 THE WITNESS: The editors</p> <p>23 would certainly be reading it,</p> <p>24 yes.</p>	<p>1 disclose and certify that the work was</p> <p>2 done was your original work.</p> <p>3 A. It's -- it's assumed that</p> <p>4 the person who's submitting it, it's</p> <p>5 their work.</p> <p>6 Q. Well, actually I've seen</p> <p>7 some notations, including in the one that</p> <p>8 you submitted in 2008, which is the only</p> <p>9 disclosure that I have that you have to</p> <p>10 certify that the work done was original</p> <p>11 work.</p> <p>12 MR. HEGARTY: Objection to</p> <p>13 form.</p> <p>14 MR. HUDSON: Objection to</p> <p>15 form.</p> <p>16 BY MR. TISI:</p> <p>17 Q. That is your work.</p> <p>18 A. So my papers that I submit</p> <p>19 for my publication is my work.</p> <p>20 Q. That wasn't my question. My</p> <p>21 question was, when you submit a paper</p> <p>22 generally, do you have to identify that</p> <p>23 the work done was your original work?</p> <p>24 MR. HEGARTY: Objection to</p>

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<p style="text-align: right;">Page 302</p> <p>1 form.</p> <p>2 THE WITNESS: Technically</p> <p>3 what happens when you do a</p> <p>4 submission, you have to say, has</p> <p>5 this work been submitted to</p> <p>6 another journal.</p> <p>7 And if the -- if that has</p> <p>8 happened, then the journal has the</p> <p>9 opportunity to decline to review</p> <p>10 that. So you would state that in</p> <p>11 the submission process, it is not</p> <p>12 being submitted to another journal</p> <p>13 simultaneously.</p> <p>14 BY MR. TISI:</p> <p>15 Q. Now, apart from disclosing a</p> <p>16 journal. We looked previously about --</p> <p>17 articles usually have either an</p> <p>18 acknowledgment section or a conflict of</p> <p>19 interest section or both in which the</p> <p>20 author acknowledges people who may have</p> <p>21 assisted in some fashion with the</p> <p>22 article, right?</p> <p>23 A. That's correct.</p> <p>24 Q. And then the conflicts of</p>	<p style="text-align: right;">Page 304</p> <p>1 A. That's correct.</p> <p>2 Q. And why is it that in the</p> <p>3 actual bodies of the article is that</p> <p>4 usually done?</p> <p>5 MR. HEGARTY: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: I'm sorry. Is</p> <p>8 it --</p> <p>9 BY MR. TISI:</p> <p>10 Q. Why do authors have to</p> <p>11 disclose or usually have to disclose</p> <p>12 their funding sources, their biases, you</p> <p>13 know, conflicts of interest?</p> <p>14 A. So.</p> <p>15 Q. And acknowledgments? Why do</p> <p>16 we have that?</p> <p>17 A. Okay. Slight technicality.</p> <p>18 That's not really within the body of the</p> <p>19 article. This is like a separate</p> <p>20 statement. I just want to clarify that.</p> <p>21 Q. That's fine.</p> <p>22 A. Okay.</p> <p>23 Q. We can -- that's fine. In</p> <p>24 the published article --</p>
<p style="text-align: right;">Page 303</p> <p>1 interest section, is something where they</p> <p>2 say -- they ask the -- that authors</p> <p>3 disclose whether or not they had any</p> <p>4 potential conflicts of interest that the</p> <p>5 reader might want to know when</p> <p>6 considering the conclusions that the</p> <p>7 authors reach?</p> <p>8 A. It wouldn't necessarily be</p> <p>9 in a separate conflict of interest</p> <p>10 headline. It would be in the</p> <p>11 acknowledgment section.</p> <p>12 Q. Okay. But somehow there are</p> <p>13 really two concepts that must be</p> <p>14 addressed. Number one is, any</p> <p>15 contributions made by people other than</p> <p>16 the named authors, and oftentimes you'll</p> <p>17 get an acknowledgment like that?</p> <p>18 MR. HEGARTY: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: That's</p> <p>21 correct.</p> <p>22 BY MR. TISI:</p> <p>23 Q. And any potential conflicts</p> <p>24 of interest?</p>	<p style="text-align: right;">Page 305</p> <p>1 A. Yes.</p> <p>2 Q. -- there's usually a section</p> <p>3 that identifies any potential conflicts,</p> <p>4 acknowledgments of contribution, or of</p> <p>5 funding?</p> <p>6 A. Yes.</p> <p>7 Q. Why do we have that? Why is</p> <p>8 that standard?</p> <p>9 A. For transparency, for the</p> <p>10 reader.</p> <p>11 Q. Why is it important that</p> <p>12 authors be transparent about what they</p> <p>13 do?</p> <p>14 A. Well, I think they -- that's</p> <p>15 a desire to do that, to acknowledge where</p> <p>16 the funding came from and be transparent</p> <p>17 about it.</p> <p>18 Q. Are there articles -- I</p> <p>19 mean, I'm thinking of a series of</p> <p>20 articles out of the New England Journal</p> <p>21 of Medicine which talk about funding</p> <p>22 source is often a source of bias in the</p> <p>23 articles.</p> <p>24 Have you ever seen that?</p>



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<p>1 MR. HEGARTY: Objection to 2 form. 3 THE WITNESS: I have not 4 seen that article. 5 BY MR. TISI: 6 Q. Okay. Are you aware -- I 7 mean, are you aware of studies that show 8 that funding source sometimes affects the 9 results that are -- that are -- that the 10 authors reach? 11 MR. HEGARTY: Objection to 12 form. 13 THE WITNESS: No, I'm not 14 aware of specific studies. 15 BY MR. TISI: 16 Q. That doesn't surprise you? 17 That wouldn't surprise you, would it? 18 A. Would it surprise me that 19 what? 20 Q. That funding source 21 affects -- can affect the outcomes that 22 are reached by the authors? 23 MR. HEGARTY: Objection to 24 form.</p>	<p>1 form. 2 THE WITNESS: I'm not 3 thinking so much of benefit. We 4 certainly do look to see the 5 funding source. 6 BY MR. TISI: 7 Q. Right. 8 A. Okay. 9 Q. Because you view and 10 evaluate the conclusions in the context 11 of does the author have a financial or 12 other interest in the subject matter? 13 A. So, yes, that's correct. 14 Q. Okay. So about peer review 15 for a minute, does the process of peer 16 review differ from journal to journal? 17 A. Yes. 18 Q. And some journals are more 19 rigorous than others, true? 20 A. Not necessarily. I will say 21 that the acceptance rates, number of 22 papers they accepted to a particular 23 journal, may be more competitive than for 24 others.</p>
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<p>1 THE WITNESS: That's a tough 2 question. I mean, I would have -- 3 I mean, it's an interesting 4 question. I would really have to 5 look at the literature in order to 6 evaluate that. 7 BY MR. TISI: 8 Q. Okay. 9 A. It's not something that I 10 can speak of. I'm aware of the topic. 11 But I can't say that I'm aware of 12 specific studies that have done 13 statistical analyses that have proven 14 bias. 15 Q. Sometimes one of the things 16 that you looked at when you read articles 17 is you're interested in who funded them, 18 right? 19 A. Yes, that's correct. 20 Q. You are also interested in 21 the relationship that the authors might 22 have to anybody who might benefit from 23 the conclusions the author reached? 24 MR. HEGARTY: Objection to</p>	<p>1 But I can't say that the 2 peer review process is more rigorous for 3 some journals than others. 4 Q. Well, peer reviewers 5 typically don't, for example -- let me 6 take one topic first. 7 So for example, if we had 8 The New England Journal of Medicine on 9 the one hand, which is a very competitive 10 journal, correct? 11 A. Yes. 12 Q. And you have another 13 journal -- let's say Anti-Cancer Research 14 which is not -- not a -- you would agree 15 that's not a big journal? 16 A. It's not a highly cited 17 journal. 18 Q. Correct. The -- a study, 19 the acceptance rates are much higher for 20 the lower impact journals than the higher 21 impact journals, correct? 22 A. The acceptance rate is much 23 lower for the high impact journals; 24 that's correct.</p>

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<p style="text-align: right;">Page 310</p> <p>1 Q. Right. So it's much harder 2 to get an article in the New England 3 Journal of Medicine than Anti-Cancer 4 Research? 5 A. Yes, that's correct. 6 Q. And I mentioned impact 7 factors. Do you know what an impact 8 factor is? 9 A. Yes. 10 Q. An impact factor is a 11 measure -- kind of a substantive measure 12 of how often a journal is cited and 13 how -- as a measure of what influence it 14 has in the medical literature? 15 A. That's correct. 16 Q. So for example, using my 17 examples, The New England Journal of 18 Medicine might have an impact factor of 19 50? 20 A. Yes. 21 Q. And anti-cancer research 22 might have an impact factor of one? 23 MR. HEGARTY: Objection to 24 form.</p>	<p style="text-align: right;">Page 312</p> <p>1 BY MR. TISI: 2 Q. So it's important to not 3 only look at, you know, in terms of 4 weighing -- we talked about weighing the 5 authors and who they are and, you know, 6 what financial interest they have, but 7 it's also, one of the things that you 8 might want to look at is, is this journal 9 really one that is one that is a highly 10 cited, highly respected journal? 11 MR. HEGARTY: Objection to 12 form. 13 THE WITNESS: I'm sorry. In 14 what context? 15 BY MR. TISI: 16 Q. One of the things that you 17 look at as a researcher is, okay, well, 18 not only do I want to see what -- what 19 the authors' conflicts are or whatever, 20 it's important to me that, you know, I 21 see whether it's in a rigorous journal 22 out there or not. 23 MR. HEGARTY: Objection to 24 form.</p>
<p style="text-align: right;">Page 311</p> <p>1 THE WITNESS: I haven't 2 looked at it recently. But it's 3 probably lower than The New 4 England Journal of Medicine. 5 BY MR. TISI: 6 Q. It's significantly lower 7 than The New England Journal of Medicine. 8 A. Yes. 9 Q. And that's a reflection 10 of -- and it's not unusual for 11 researchers to say, look, you want to get 12 your article in the highest impact 13 journal, right? That would be the goal? 14 A. No, not necessarily. 15 Q. Okay. But it is easier to 16 get -- I mean, if you've shopped around 17 an article on a -- to a couple journals 18 and it doesn't -- it is not accepted, you 19 know, you can always find a home for a 20 journal? 21 MR. HEGARTY: Objection to 22 form. 23 THE WITNESS: So it's -- 24 these days, that's probably true.</p>	<p style="text-align: right;">Page 313</p> <p>1 THE WITNESS: So the impact 2 factor isn't necessarily a 3 reflection of the rigor of the 4 journal and the journal review. 5 BY MR. TISI: 6 Q. Well, it might be a 7 reflection of the number of times it's 8 cited, correct? 9 A. That's correct. 10 Q. And the number of times the 11 journal is cited is -- is a collective 12 understanding of the medical and 13 scientific community of, okay, an article 14 in Anti-Cancer Research, okay, it's good 15 enough, but, you know, if I have another 16 article on the topic in JAMA, or The New 17 England Journal of Medicine, that tells 18 me something? 19 MR. HEGARTY: Objection to 20 form. 21 THE WITNESS: So I 22 understand the point that you're 23 trying to make. And so let me 24 clarify that.</p>



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<p>1 So, for example, New England 2 Journal of Medicine and JAMA, the 3 types of articles that they prefer 4 are primarily randomized clinical 5 trials. 6 So there is a great deal of 7 research out there that's not 8 randomized clinical trials. So 9 they wouldn't qualify for The New 10 England Journal of Medicine. They 11 also wouldn't qualify because they 12 may be specialty topics. 13 So in most areas, most 14 people who are working in a 15 particular research area, they 16 will be publishing in journals 17 that will have a lower impact than 18 The New England Journal of 19 Medicine, because those are -- 20 those are in specialty areas. 21 Those are not as widely read. 22 But for those people in 23 those areas, those journals that 24 they are publishing in are</p>	<p>1 epidemiology. So that we understand the 2 topics that come afterwards, there are 3 several different kind of studies. 4 We have a case-control 5 study, and that's where you have -- you 6 look backwards at cases and controls and 7 you do some statistical analysis, 8 correct? 9 A. That's correct. 10 Q. Kind of like the study you 11 proposed to Johnson &amp; Johnson back in the 12 1990s? 13 A. Yes. 14 Q. Okay. Then you have cohort 15 studies, where you kind of look at, you 16 kind of look forward, right? 17 A. That's correct. 18 Q. You basically, you know, go 19 to a hospital for example and you follow 20 people going forward, right? That's a 21 kind of -- that's a kind of epidemiology 22 study? 23 A. That's correct. 24 Q. And when looking at issues,</p>
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<p>1 considered respected. 2 BY MR. TISI: 3 Q. Well, but -- I don't want 4 there to be any misconception in the 5 record. You're not suggesting in any 6 fashion that The New England Journal of 7 Medicine or Lancet or JAMA don't publish 8 epidemiology studies? 9 A. They do on occasion. 10 Q. Okay. Right. So in fact, 11 you tried to submit one of your -- we 12 talked about that before. You tried to 13 submit one of your articles to, to the 14 Lancet, and it was rejected, true? 15 MR. HEGARTY: Objection to 16 form. 17 BY MR. TISI: 18 Q. Critical review? 19 A. No. 20 Q. Or was it JAMA? 21 A. Neither. 22 Q. Okay. We'll talk about that 23 in a minute. 24 So we mentioned</p>	<p>1 even though you have sometimes noted the 2 benefits and the comparative benefits and 3 problems -- because there's no perfect 4 study, right? 5 MR. HEGARTY: Objection to 6 form. 7 BY MR. TISI: 8 Q. Everything has issues to 9 consider? 10 A. So there are often biases 11 and flaws in studies, yes. 12 Q. We can identify them. But 13 there's no perfect study out there, 14 right? 15 A. So -- except for mine, of 16 course. 17 Q. We'll talk -- we're going to 18 talk about that in a little bit. 19 A. Okay. Okay. 20 Q. I think you -- I think you 21 see that coming. 22 A. Okay, yes. Okay. 23 Q. So but my question, Doctor, 24 is, when given the opportunity, okay, to</p>

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<p style="text-align: right;">Page 318</p> <p>1 study talc, two kinds of studies you 2 proposed to Johnson &amp; Johnson, a 3 case-control study, right? 4 A. Yes. 5 Q. And you suggested a 6 meta-analysis which you actually did? 7 MR. HEGARTY: Objection to 8 form. 9 BY MR. TISI: 10 Q. You did one on diaphragms, 11 but what was actually done, correct? 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: I'm sorry. 15 Are you referring to my -- when I 16 met with Dr. Wynder? That was a 17 case-control study. 18 BY MR. TISI: 19 Q. That was case-control. 20 A. Right. 21 Q. But you've also done 22 meta-analyses on the issues to talc as 23 well? 24 A. That meta-analysis was</p>	<p style="text-align: right;">Page 320</p> <p>1 THE WITNESS: So that -- 2 back when I met with Don Jones and 3 John Hopkins with Dr. Wynder back 4 in 1995, that was a hospital-based 5 study. 6 BY MR. TISI: 7 Q. But it was a case-control 8 study? 9 A. That's correct. 10 Q. Now, we are going to talk 11 about issues related to statistics and 12 all that, and I don't want to get too 13 bogged down. But a statistical analysis 14 done by somebody like you, there are 15 several concepts that I want to at least 16 explore. 17 Let's say I have a relative 18 risk of let's say 1.5. Okay. And that 19 means to a -- somebody like you, that 20 there's a 50 percent increased 21 association between what you're looking 22 at and the null hypothesis, correct? 23 MR. HEGARTY: Objection to 24 form.</p>
<p style="text-align: right;">Page 319</p> <p>1 performed, that's correct. 2 Q. So, again, so the jury 3 understands, a meta-analysis is taking a 4 bunch of different studies, combining 5 them together to try to increase the 6 power of the study to detect what you're 7 looking for? 8 MR. HEGARTY: Objection to 9 form. 10 THE WITNESS: That's one of 11 its objectives. 12 BY MR. TISI: 13 Q. Okay. Have you ever 14 recommended that -- in 25 years, that the 15 company do a cohort study on issues 16 related to talc? 17 MR. HEGARTY: Objection to 18 form. 19 THE WITNESS: No. 20 BY MR. TISI: 21 Q. Have you ever suggested that 22 they do a hospital study? 23 MR. HEGARTY: Objection to 24 form.</p>	<p style="text-align: right;">Page 321</p> <p>1 THE WITNESS: So, that's 2 partially correct. You know, the 3 relative risk is usually presented 4 in combination with, for example, 5 like a P-value. 6 BY MR. TISI: 7 Q. And we'll talk about 8 P-values. 9 A. Okay. 10 Q. But I just want to 11 understand what the number -- if it says 12 1.5, that's a 50 percent increased risk? 13 A. That's correct. 14 Q. And the next thing that you 15 typically want to do is look at whether 16 it's what we call statistically 17 significant, correct? 18 A. Yes. 19 Q. And statistical significance 20 is a -- somebody who does a study, 21 usually expresses it to a .05 P-value? 22 A. So that's the convention. 23 Q. Right. And that means that 24 if we toss a coin 95 times out of 100,</p>

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<p style="text-align: right;">Page 322</p> <p>1 that you would get the same results, and 2 five times you wouldn't? 3 A. It means that five times the 4 result may occur by chance. 5 Q. By chance. And that's a 6 convention. But we know -- we've 7 talked -- I've seen you refer to 8 Dr. Rothman oftentimes. You recognize 9 him as an expert in the area of 10 epidemiology, correct? 11 MR. HEGARTY: Objection to 12 form. 13 MR. HUDSON: Objection to 14 form. 15 THE WITNESS: He's written a 16 textbook on epidemiology. 17 BY MR. TISI: 18 Q. And you've referred to that 19 in your articles, correct? 20 A. Okay, right. I'd have to 21 see it. But... 22 Q. That wouldn't surprise you? 23 MR. HEGARTY: Objection to 24 form.</p>	<p style="text-align: right;">Page 324</p> <p>1 error, that your, whatever your relative 2 risk is -- let's say the standard is 3 95 percent confidence, that it would be, 4 because of sampling variability, your 5 relative risk could be quite different. 6 It could fall within a range of values. 7 Q. And typically speaking, the 8 idea is if the confidence interval falls 9 below one, it's not considered 10 statistically significant? 11 A. If the -- if the risk is 12 elevated above one and the confidence 13 interval falls below one, that would be 14 correct. 15 Q. Now, are you familiar, are 16 you a member of the American Statistical 17 Association? 18 A. No. 19 Q. Do you know what they are? 20 A. I've heard of it. 21 Q. Do you know that there's 22 been a significant discussion in the 23 epidemiology community about the 24 significance of P-values and confidence</p>
<p style="text-align: right;">Page 323</p> <p>1 THE WITNESS: I'd have to 2 see what the context is. 3 BY MR. TISI: 4 Q. Well, in one of them you 5 just cite the textbook. So I can't know 6 the context, because you just cited it 7 generally in your article, and nobody 8 could figure out what your methods are 9 because you didn't cite to a particular 10 section. We'll talk about that later. 11 MR. SILVER: Objection to 12 form. 13 MR. HUDSON: Objection to 14 form. 15 No question pending. 16 BY MR. TISI: 17 Q. So let's talk about -- we 18 talked about P-value. Let's talk about 19 confidence intervals. 20 Confidence intervals are 21 what? 22 A. So it's related, it's 23 related to the P-value concept. It just 24 basically means that given sampling</p>	<p style="text-align: right;">Page 325</p> <p>1 intervals? 2 A. I think that that's a topic 3 that, you know, that has been discussed 4 before. 5 Q. And Dr. Rothman has been a 6 real proponent of looking beyond 7 simply -- I think he uses the word 8 slavish adherence to P-values and 9 confidence intervals to look for risks? 10 MR. HEGARTY: Objection to 11 form. 12 MR. HUDSON: Objection to 13 form. 14 BY MR. TISI: 15 Q. Have you ever seen that? 16 A. So I don't recall reading a 17 specific article on that. 18 Q. But you know -- you know 19 that he's been somebody who talks about 20 that a lot? 21 A. No, not especially. 22 Q. Okay. So if something 23 has -- and if you have -- a point 24 estimate is the same thing as a relative</p>



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<p>1 risk --</p> <p>2 A. That's correct.</p> <p>3 Q. -- the number in the middle,</p> <p>4 right? So if you have a relative risk</p> <p>5 of -- let's kind of use it here. I'll</p> <p>6 turn this over. You have a 1.5 RR with a</p> <p>7 confidence interval of, let's say, 99,</p> <p>8 right, to 1.89, with a P-value of .05.</p> <p>9 That's a lot of gobbledygook.</p> <p>10 But what you're basically</p> <p>11 saying is that one possible outcome is</p> <p>12 that there's a very small chance that</p> <p>13 this is related to chance, but most of</p> <p>14 the risk estimates are between 1 and 1.9?</p> <p>15 MR. HUDSON: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: It means that</p> <p>18 that's the range of possible</p> <p>19 values that you would expect for</p> <p>20 sampling error.</p> <p>21 BY MR. TISI:</p> <p>22 Q. But statistically speaking,</p> <p>23 the true result is closer to the point</p> <p>24 estimate than at the tail end of the</p>	<p>1 intervals, correct?</p> <p>2 A. The confidence interval is a</p> <p>3 reflection of the P-value.</p> <p>4 Q. Right. And you don't throw</p> <p>5 out a result like this -- you don't</p> <p>6 ignore a result like I just put out and</p> <p>7 wrote out here just because the value</p> <p>8 crosses one and gets to .199. That</p> <p>9 doesn't make sense, does it?</p> <p>10 MR. HEGARTY: Objection to</p> <p>11 form.</p> <p>12 THE WITNESS: So I wouldn't</p> <p>13 throw it out. I'm sorry. I don't</p> <p>14 quite understand.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Let's say you have -- let's</p> <p>17 say you have a lot of other data out</p> <p>18 there that shows an RR of 2.0.</p> <p>19 And it's all statistically</p> <p>20 significant. Then you have this one</p> <p>21 result over here that's .99 to .185.</p> <p>22 These aren't necessarily inconsistent,</p> <p>23 are they?</p> <p>24 MR. HEGARTY: Objection to</p>
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<p>1 confidence interval, correct?</p> <p>2 A. That's the measured result,</p> <p>3 the 1.5.</p> <p>4 Q. Right. And that's -- that's</p> <p>5 considered by statisticians and people</p> <p>6 who do the work that you do, that's</p> <p>7 considered to be the most accurate place</p> <p>8 where the real risk lies?</p> <p>9 MR. HEGARTY: Objection to</p> <p>10 form.</p> <p>11 MR. HUDSON: Objection to</p> <p>12 form.</p> <p>13 THE WITNESS: So I</p> <p>14 wouldn't -- I wouldn't call it</p> <p>15 that. I would say that is --</p> <p>16 that's the finding from the study.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Right. But that's the most</p> <p>19 likely event, the point estimate is the</p> <p>20 most likely --</p> <p>21 A. That's what the data show.</p> <p>22 Q. That's correct. Okay. And</p> <p>23 if you were to change the .05 to say .06</p> <p>24 that would change the confidence</p>	<p>1 form.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Just because this crosses</p> <p>4 one doesn't mean that this -- that this</p> <p>5 1.5 is inconsistent with the 2.0?</p> <p>6 MR. HEGARTY: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: There are --</p> <p>9 they're from two separate studies?</p> <p>10 Is that the --</p> <p>11 BY MR. TISI:</p> <p>12 Q. Yeah.</p> <p>13 A. Yeah, so they are from two</p> <p>14 separate studies.</p> <p>15 Q. Right. But they're not --</p> <p>16 what I'm saying is --</p> <p>17 A. The one study doesn't have</p> <p>18 anything to do with the other study.</p> <p>19 Q. But if you're trying to look</p> <p>20 for an issue of consistency, those are</p> <p>21 not inconsistent results, are they?</p> <p>22 MR. HEGARTY: Objection to</p> <p>23 form.</p> <p>24 BY MR. TISI:</p>



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<p style="text-align: right;">Page 330</p> <p>1 Q. You don't throw this result 2 out because -- this 1.5 out because it is 3 statistically insignificant to a 4 confidence interval of .99 to 1.89. 5 You'd look at it in the confidence of 6 everything else, right? 7 MR. SILVER: Objection to 8 form. 9 THE WITNESS: It wouldn't be 10 thrown out. It would be reported 11 as such. 12 BY MR. TISI: 13 Q. Right. You would look at it 14 in the context of all the other evidence 15 together, correct? 16 MR. HEGARTY: Objection to 17 form. 18 BY MR. TISI: 19 Q. Yes? 20 A. So all the evidence within 21 that particular study? 22 Q. No. All the other evidence, 23 if there's multiple studies, you want to 24 look at -- you want to look at all the</p>	<p style="text-align: right;">Page 332</p> <p>1 literature. 2 Q. Okay. And hopefully by 3 combining the results of different 4 studies, you get a better picture of what 5 the risk is, correct? 6 MR. HEGARTY: Objection to 7 form. 8 BY MR. TISI: 9 Q. In other words, let me -- 10 A. Can I answer? 11 Q. Yeah. Absolutely. 12 A. So that's -- that's part of 13 the -- I want to make sure. That's part 14 of the meta-analysis is that, is also -- 15 right, to identify heterogeneity because 16 there wouldn't be -- like, if every 17 single study, let's say you had 100 18 studies that had 1.5, there wouldn't be 19 any point in doing it, right? 20 So meta-analysis, one of the 21 things that you do is try and come up 22 with a summary risk. But also to 23 identify if there are differences between 24 studies, you know, what could account for</p>
<p style="text-align: right;">Page 331</p> <p>1 relative risks, put them together and 2 see, you know, how they kind of line up, 3 right? 4 A. I guess it depends on what 5 your purpose is. So usually in a single 6 study there may be multiple ways of 7 analyzing data. 8 Q. Let's talk about 9 meta-analysis for a little bit. Why do 10 we do meta-analyses? 11 MR. HEGARTY: Objection to 12 form. 13 THE WITNESS: So why do we 14 personally? 15 BY MR. TISI: 16 Q. Yeah. Why do you do it? 17 A. I don't do it that often. 18 But the purpose of meta-analysis is to -- 19 kind of -- is to come up with sort of a 20 way of synthesizing the literature. If 21 there's a big topic with a lot of 22 different results on a similar topic, 23 meta-analysis is a quantitative tool to 24 summarize the results of a body of</p>	<p style="text-align: right;">Page 333</p> <p>1 that. 2 Q. So you're not only 3 looking -- so on one hand you want to 4 look for what the overall potential risk 5 is, but you also want to be able to 6 identify, for example, biases or 7 confounding factors or those kinds of 8 things, which you might not see in any 9 individual study? 10 MR. HEGARTY: Objection to 11 form. 12 THE WITNESS: There could be 13 different reasons for looking at 14 way -- it could be study location, 15 for example. 16 BY MR. TISI: 17 Q. Okay. 18 A. Okay. 19 Q. So do you agree that 20 researchers doing meta-analyses should 21 report their methods with sufficient 22 detail to allow for replication? 23 A. Yes. 24 Q. Why is replication</p>



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<p style="text-align: right;">Page 334</p> <p>1 important?</p> <p>2 A. So the purpose of</p> <p>3 meta-analysis is to attempt to the best</p> <p>4 extent possible to get all the relevant</p> <p>5 articles within that body of literature</p> <p>6 and analyze.</p> <p>7 And then to list that, be</p> <p>8 open about it, and so that way, if</p> <p>9 anybody else wants to do their own</p> <p>10 meta-analysis, they can see which ones</p> <p>11 you've identified and see whether you</p> <p>12 come up with a similar finding.</p> <p>13 Q. Do you agree that</p> <p>14 consulting -- conducting a sound and</p> <p>15 credible meta-analysis involves a</p> <p>16 replicable literature search strategy?</p> <p>17 MR. HEGARTY: Objection to</p> <p>18 form.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Go ahead.</p> <p>21 A. It does require a literature</p> <p>22 search strategy.</p> <p>23 Q. Okay.</p> <p>24 A. And that strategy should be</p>	<p style="text-align: right;">Page 336</p> <p>1 form.</p> <p>2 THE WITNESS: So I'm not</p> <p>3 sure that the specific -- I mean</p> <p>4 maybe the weights are disclosed.</p> <p>5 I think the method of</p> <p>6 meta-analysis should be described.</p> <p>7 BY MR. TISI:</p> <p>8 Q. Well, without knowing the</p> <p>9 weights that the authors gave to a</p> <p>10 particular study, how could somebody</p> <p>11 replicate a meta-analysis? Let me</p> <p>12 rephrase the question.</p> <p>13 A. Yes.</p> <p>14 Q. I want to be clear. In</p> <p>15 order -- you said before that being able</p> <p>16 to replicate a meta-analysis is an</p> <p>17 important thing as part of a paper. You</p> <p>18 need to know the methodology that's been</p> <p>19 used.</p> <p>20 A. That's correct.</p> <p>21 Q. Okay. In order to replicate</p> <p>22 a meta-analysis, someone would need to</p> <p>23 know the risk estimates in the original</p> <p>24 studies, correct?</p>
<p style="text-align: right;">Page 335</p> <p>1 explained.</p> <p>2 Q. Do you agree that conducting</p> <p>3 a sound and credible meta-analysis</p> <p>4 involves a listing or graphical display</p> <p>5 of individual study -- individual study</p> <p>6 results or inputs?</p> <p>7 A. So that's often convention</p> <p>8 these days, is to list out the individual</p> <p>9 study results in a graph.</p> <p>10 Q. How about the weights that</p> <p>11 are given to each study when you do --</p> <p>12 because all -- when you do a study, one</p> <p>13 of the things that you have to do is</p> <p>14 determine -- not all studies are going to</p> <p>15 be treated exactly the same. So the</p> <p>16 person conducting the meta-analysis has</p> <p>17 to assign weights to each of the studies,</p> <p>18 correct?</p> <p>19 A. They are weighted.</p> <p>20 Q. Okay. And the methodology</p> <p>21 for weighting the studies should be</p> <p>22 disclosed, correct? And the weight given</p> <p>23 to each study should be disclosed?</p> <p>24 MR. HEGARTY: Objection to</p>	<p style="text-align: right;">Page 337</p> <p>1 A. That's correct.</p> <p>2 Q. And you can get those from</p> <p>3 the original studies. You can find that</p> <p>4 in the studies, correct?</p> <p>5 A. That's correct.</p> <p>6 Q. Okay. Number 2, the</p> <p>7 confidence interval from those original</p> <p>8 studies?</p> <p>9 A. I'm sorry, what was that?</p> <p>10 Q. The confidence intervals</p> <p>11 from those original studies, correct?</p> <p>12 A. That's one way of doing it</p> <p>13 right.</p> <p>14 Q. And the other one, you need</p> <p>15 to know the method of weighting -- the</p> <p>16 individual weights given to the studies?</p> <p>17 A. That would go into</p> <p>18 meta-analysis, right.</p> <p>19 Q. Okay. And that's the only</p> <p>20 one of those three things that the person</p> <p>21 doing the meta-analysis -- it's not in</p> <p>22 the original studies, because those are</p> <p>23 not meta-analyses. So that's the one key</p> <p>24 that you need to know in order to</p>

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<p style="text-align: right;">Page 338</p> <p>1 replicate a meta-analysis; you need to 2 know how did the -- either how did the 3 author go about assigning the weights or 4 what the weights were that the author 5 assigned? 6 MR. HEGARTY: Objection to 7 form. 8 THE WITNESS: So can you 9 repeat the question? 10 BY MR. TISI: 11 Q. Let me phrase it a different 12 way. 13 A. Okay. 14 Q. Okay. If you don't know the 15 weights that the person doing the 16 meta-analysis assigned to the particular 17 studies that made part of that 18 meta-analysis, or if the author does not 19 disclose the methodology that they used 20 to assign those weights, is there any way 21 for the reader to replicate what the 22 author did? 23 MR. HEGARTY: Objection to 24 form.</p>	<p style="text-align: right;">Page 340</p> <p>1 failure to control it leads to any 2 important bias? 3 MR. HEGARTY: Objection to 4 form. 5 THE WITNESS: I'm sorry. 6 Can you repeat that, please? 7 BY MR. TISI: 8 Q. Yeah. Do you agree with the 9 statement that just because a variable 10 has a potential to confound does not mean 11 that failure to control it leads to any 12 important bias? 13 MR. HEGARTY: Objection to 14 form. 15 THE WITNESS: I think it 16 depends on the circumstances. 17 BY MR. TISI: 18 Q. Okay. Thinking about a 19 meta-analysis methodology in general, 20 would you agree that a meta-analysis is 21 important to compare like with like? 22 A. Can you be a little more 23 clearer on that? I'm not sure what that 24 -- right.</p>
<p style="text-align: right;">Page 339</p> <p>1 THE WITNESS: So I'm not 2 entirely sure. You know, there 3 are different ways, I'm not a -- 4 meta-analysis. But there are 5 different ways of doing the 6 meta-analyses. 7 So there are reference 8 methods for it, which then 9 describes the weights. So you'd 10 use a software package. 11 BY MR. TISI: 12 Q. Which software package did 13 you use? 14 A. I don't really use a 15 software package. 16 Q. Which software package with 17 Dr. Huncharek use? 18 MR. HEGARTY: Objection to 19 form. 20 THE WITNESS: I don't know. 21 BY MR. TISI: 22 Q. Do you agree with the 23 statement just because a variable has a 24 potential to confound does not mean the</p>	<p style="text-align: right;">Page 341</p> <p>1 Q. Yeah. Let's say, for 2 example, you have a study on smokers. 3 A. Mm-hmm. 4 Q. And you have a study that 5 compares -- that looks at a risk with 6 pack-years. 7 A. Mm-hmm. 8 Q. Okay. And then you have 9 another study that compare -- talks about 10 the number of cigarettes smoked a month. 11 A. Right. 12 Q. Those are two different 13 measurements, right? 14 A. Right. That's correct. 15 Q. You can't -- if you're 16 comparing -- if you're trying to figure 17 out, for example, dose-response in the 18 context of a cigarette, you would want -- 19 you can't compare pack-years, which is 20 duration of use, and number of cigarettes 21 per month, frequency of use? 22 MR. HEGARTY: Objection to 23 form. 24 THE WITNESS: That's</p>

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<p style="text-align: right;">Page 342</p> <p>1 correct.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Do you agree that because</p> <p>4 many factors, both methodologic and</p> <p>5 biologic, could affect the relative risk</p> <p>6 estimates, homogeneity assumption is at</p> <p>7 best at convenient fiction?</p> <p>8 MR. HEGARTY: Objection to</p> <p>9 form.</p> <p>10 THE WITNESS: I don't know</p> <p>11 what that means.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Okay. Do you agree that an</p> <p>14 important element of a meta-analysis is</p> <p>15 the precise specification of the exposure</p> <p>16 under study?</p> <p>17 A. That is important.</p> <p>18 Q. Do you agree with the</p> <p>19 statement, meta-analysis can be reviewed</p> <p>20 as the transference of good analytic</p> <p>21 practice from the single study to the</p> <p>22 multiple study context. It begins</p> <p>23 through critical evaluation of the</p> <p>24 available data in a manner that is</p>	<p style="text-align: right;">Page 344</p> <p>1 use a variances estimator in your</p> <p>2 studies?</p> <p>3 A. I haven't done a</p> <p>4 meta-analysis in a long time. I don't</p> <p>5 remember what the term refers to.</p> <p>6 Q. What is a Forest plot?</p> <p>7 A. So a Forest plot is a --</p> <p>8 it's a graph that lays out the risk</p> <p>9 estimates for each of the individual</p> <p>10 studies.</p> <p>11 Q. With the confidence</p> <p>12 intervals?</p> <p>13 A. With confidence intervals.</p> <p>14 Q. Would you agree that</p> <p>15 presenting Forest plots is a pretty</p> <p>16 standard for meta-analysis publications?</p> <p>17 A. I think it's pretty common.</p> <p>18 Q. You don't present any</p> <p>19 graphical displays in your meta-analyses,</p> <p>20 do you? Did you do it in your study on</p> <p>21 diaphragms?</p> <p>22 MR. HEGARTY: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: I'd have to</p>
<p style="text-align: right;">Page 343</p> <p>1 explicit and fully replicable by others.</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 THE WITNESS: So I think</p> <p>5 what that statement is referring</p> <p>6 to is how is the meta-analysis</p> <p>7 done, how were the exposures</p> <p>8 characterized, how was the</p> <p>9 literature search was done, what</p> <p>10 specific search engines are</p> <p>11 doing -- what specific search</p> <p>12 engines were used, which data was</p> <p>13 abstracted from the studies,</p> <p>14 because often it's not entirely</p> <p>15 clear as to what the specific data</p> <p>16 points you should be extracting.</p> <p>17 So I think those things</p> <p>18 are -- should be spelled out in a</p> <p>19 meta-analysis.</p> <p>20 BY MR. TISI:</p> <p>21 Q. What is the variances</p> <p>22 estimate?</p> <p>23 A. So that I don't recall.</p> <p>24 Q. Do you always use -- do you</p>	<p style="text-align: right;">Page 345</p> <p>1 look at that.</p> <p>2 BY MR. TISI:</p> <p>3 Q. We'll talk about that in a</p> <p>4 minute.</p> <p>5 Did you -- do you know</p> <p>6 whether you reported on the individual</p> <p>7 study weights for the individual studies</p> <p>8 considered?</p> <p>9 A. For which study?</p> <p>10 Q. Let's say your</p> <p>11 meta-analysis, your diaphragm study?</p> <p>12 MR. HEGARTY: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: You're talking</p> <p>15 about the published Huncharek</p> <p>16 study?</p> <p>17 BY MR. TISI:</p> <p>18 Q. Yes.</p> <p>19 A. I'd have to go back and look</p> <p>20 at that.</p> <p>21 Q. We'll talk about this for a</p> <p>22 minute, but the 2003 Huncharek study does</p> <p>23 not list the weights given by</p> <p>24 Dr. Huncharek to each of the studies. In</p>

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<p style="text-align: right;">Page 346</p> <p>1 order to replicate what he did, would you 2 need to know what weight he assigned to 3 each of the studies? 4 MR. HEGARTY: Objection to 5 form. 6 THE WITNESS: No, I don't 7 think it's necessary. I think you 8 need the raw data. You need the 9 actual raw data and either the 10 confidence interval or the 11 standard error in order to 12 replicate it. 13 There's a -- and I don't 14 know, because it's not my area, 15 but there's a methodology that 16 applies where the weights are 17 based upon the standard error. 18 But I just -- I just can't recall 19 off the top of my head what that 20 is. 21 BY MR. TISI: 22 Q. Let's talk about homo -- 23 heterogeneity in meta-analysis. How do 24 you interpret a Q value? Do you know</p>	<p style="text-align: right;">Page 348</p> <p>1 about this a little bit before, but I 2 just want to make clear that we have it 3 all in one place. This is Number 24. 4 Now, this article appeared 5 in the journal entitled -- I'm sorry I 6 want to get it right -- European Journal 7 of Cancer Prevention, correct? 8 A. Yes. No, I'm sorry -- yes, 9 that's correct. 10 Q. And you listed your author 11 affiliation with MRG? 12 MR. HEGARTY: Objection to 13 form. 14 BY MR. TISI: 15 Q. Meta-Analysis Research 16 Group? 17 A. So my affiliation's listed 18 as Penn State University. 19 Q. Okay. But you were also -- 20 when you originally wrote this paper for 21 the FDA, you also -- well, when 22 Dr. Huncharek and you signed your name to 23 it on behalf of -- 24 A. Yes.</p>
<p style="text-align: right;">Page 347</p> <p>1 what a Q value is? 2 A. It's a test of homogeneity. 3 Q. Did your 2003 paper measure 4 heterogeneity? 5 MR. HEGARTY: Objection to 6 form. 7 MR. HUDSON: Objection to 8 form. 9 BY MR. TISI: 10 Q. I'm sorry. Do you know 11 whether Dr. Huncharek's 2003 paper 12 measured heterogeneity? You can take it 13 out if you want. It's right in your 14 book. 15 A. I'm sorry. Which -- 16 Q. Actually, let me just move 17 forward. 18 I want to get through some 19 of those concepts. Let's talk about some 20 of the articles that you published in the 21 context of some of the things that we 22 just talked about. 23 I'd like to you look at the 24 2011 published study. And we talked</p>	<p style="text-align: right;">Page 349</p> <p>1 Q. -- it was on behalf of MRG. 2 I think we looked at that before, 3 correct? 4 MR. HEGARTY: Objection to 5 form. 6 THE WITNESS: So I -- did we 7 actually look at that? Did we 8 actually review that? 9 BY MR. TISI: 10 Q. Yeah. Let's take a look at 11 that. 12 A. Okay. 13 Q. If you want to take a look 14 at that, I believe it's number eight in 15 your binder. And I can actually give it 16 to you as well. 17 (Document marked for 18 identification as Exhibit 19 Muscat-25.) 20 MR. TISI: This is Number 21 25. 22 BY MR. TISI: 23 Q. Sir, if you look side by 24 side with these. Actually, if you go to</p>



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<p style="text-align: right;">Page 350</p> <p>1 Page 4 of this document that you have up 2 here, which is Exhibit Number 25. This 3 is the comments on the Citizen's 4 Petition, correct? 5 A. Yes. 6 Q. Okay. And you participated 7 in this? 8 MR. HEGARTY: Objection to 9 form. 10 BY MR. TISI: 11 Q. Do you see that? 12 A. Yes, I see that. 13 Q. Okay. And if you look at -- 14 let's look at, for example, if you would 15 go to Page 3 of -- excuse me -- 6 of 39 16 on the Citizen's Petition and Number 1 on 17 the article here. Do you see at the very 18 bottom left-hand corner it says, "On 19 May 3, 2008, Samuel Epstein, M.D. 20 submitted a petition to the commissioner 21 of the Food and Drug Administration." 22 Correct? Do you see all 23 that -- 24 MR. HEGARTY: Object to</p>	<p style="text-align: right;">Page 352</p> <p>1 will tell you as you go through it -- go 2 to the next page. Go to the next page of 3 the other -- of the other article as 4 well. It says, "In 1965, Hill published 5 a landmark study." 6 Do you see that? 7 A. Yes. 8 Q. It also appears in this 9 article in 2011, correct? First column 10 next page? 11 Do you see it? 12 A. Yeah, I see that. 13 Q. Next paragraph. It says, 14 "Although Hill criteria." 15 Do you see that? 16 A. Yeah. 17 Q. That also appears, right? 18 A. Yes. 19 Q. And I will tell you that as 20 you go through it, the exact same 21 language appears in both -- in both the 22 Citizen's Petition and the article? 23 MR. HEGARTY: Objection to 24 form.</p>
<p style="text-align: right;">Page 351</p> <p>1 form. 2 THE WITNESS: Yes, I see 3 that. 4 BY MR. TISI: 5 Q. -- whole paragraph? 6 A. Yes. 7 Q. Okay. And you see that in 8 the same -- same paragraph as in the 9 Citizen's Petition, correct? 10 A. Yes. 11 Q. And if you look at -- let's 12 go to -- and I'm going to tell you this 13 is all over the place here. 14 If you go to page -- Page 24 15 of the -- do you see the paragraph that 16 begins, "The issues articulated"? 17 Do you see that paragraph? 18 A. Yes. 19 Q. Okay. Do you see -- look at 20 the first -- the article first -- first 21 beginning with, "The issues articulated." 22 A. Yes. 23 Q. I'll represent to you that 24 it's the exact same paragraph. And I</p>	<p style="text-align: right;">Page 353</p> <p>1 BY MR. TISI: 2 Q. Did you know that? 3 A. So I have not sat down and 4 done a paper-by-paper comparison. 5 Q. But you know that this 6 particular article came out of the 7 Citizen's Petition that you filed on 8 behalf of the PCPC in 2009 or was filed 9 on your behalf? 10 MR. HEGARTY: Objection to 11 form. 12 THE WITNESS: So no, 13 actually. 14 BY MR. TISI: 15 Q. Okay. We'll let the jury go 16 through this and figure it out themselves 17 if they need to. 18 A. Okay. 19 MR. SILVER: Objection. 20 Move to strike. 21 MR. HUDSON: Objection to 22 form. 23 BY MR. TISI: 24 Q. So going back to the</p>



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<p style="text-align: right;">Page 354</p> <p>1 article, it's published in the journal of 2 the European Journal of Cancer 3 Prevention. 4 The article says that it was 5 submitted by you and Dr. Huncharek in 6 March 11, 2011, and accepted on 7 April 1st, 2011, correct? 8 A. Yes. 9 Q. Okay. And by that time, you 10 were litigation experts, both for Johnson 11 &amp; Johnson. We talked about that before. 12 A. Yes. 13 MR. HEGARTY: Objection to 14 form. 15 BY MR. TISI: 16 Q. And by this time you had 17 been -- you had written not only this 18 paper for the PCPC, right, you wrote 19 it -- you had written prior reports for 20 The Weinberg Group, correct? 21 MR. HUDSON: Objection to 22 form. 23 BY MR. TISI: 24 Q. On this issue?</p>	<p style="text-align: right;">Page 356</p> <p>1 BY MR. TISI: 2 Q. Now, the primary person who 3 wrote this article was Dr. Huncharek, 4 correct? 5 A. That's correct. 6 Q. The 2011? 7 A. That's correct. 8 Q. What -- what part of this 9 article did you write, if any? 10 A. So he did the majority of 11 the writing. And probably almost -- I 12 don't know exact percent. But mostly it 13 was written by him, that's correct. 14 Q. Any part of it you can 15 identify that was written by you? 16 A. I don't think I can go back 17 in time and pull out specific -- 18 Q. I'm not asking about 19 specifics. I'm talking about any 20 section, any parts of it that you feel 21 like you had a substantive contribution 22 to? 23 A. So he did most of the 24 writing, probably all of the writing. We</p>
<p style="text-align: right;">Page 355</p> <p>1 A. I wrote a prior report to 2 The Weinberg Group. 3 Q. And of course we looked at 4 that, and it was submitted on behalf of 5 the PCPC, correct? 6 MR. HEGARTY: Objection to 7 form. 8 THE WITNESS: That's 9 correct. CTFA. 10 BY MR. TISI: 11 Q. CTFA. Between 2009 and 12 2011, we looked at the privilege log, and 13 there were multiple communications with 14 Shook Hardy &amp; Bacon that were withheld 15 from us. 16 I'm not asking what you 17 communicated with your lawyers. But did 18 you submit this paper or do you know if 19 this paper was submitted to Shook Hardy &amp; 20 Bacon for -- Shook Hardy &amp; Bacon for 21 review? 22 MR. HEGARTY: Objection to 23 form. 24 THE WITNESS: No.</p>	<p style="text-align: right;">Page 357</p> <p>1 may have, and I don't remember 2 specifically, but we probably discussed 3 at some point, I probably looked at it 4 for review and said it looked fine. 5 Q. Now, the prior publication 6 or the thing that was sent to the FDA, 7 the report that was sent to the FDA, did 8 he write that as well? 9 MR. HEGARTY: Objection to 10 form. 11 THE WITNESS: The Citizen's 12 Petition? 13 BY MR. TISI: 14 Q. The response to the 15 Citizen's Petition? 16 A. That's correct. He wrote 17 most of it. 18 Q. Can you identify parts of 19 the Citizen's Petition that you wrote? 20 A. So I did the graphs. So it 21 was the analysis of SEER rates of ovarian 22 cancer. 23 Q. Other than that, anything 24 else?</p>



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<p>1 A. So that was -- that was 2 mostly what I did. 3 Q. I'm sorry. Go ahead. 4 A. I don't have any specific 5 recollection, but I probably reviewed it 6 for its contents and it was sent off. 7 Q. The SEER graph really shows 8 that there's been no decrease in the 9 number of ovarian cancer cases over time 10 as cornstarch was used instead of talc in 11 cosmetic products? 12 A. It shows that the rates of 13 ovarian cancer are stable. 14 Q. Right. And that was your 15 major contribution to this -- to this 16 paper? 17 A. Yes. 18 Q. Now, going back to the 2011 19 article -- the 2011 article, do you know 20 if it was submitted to any paper, any 21 journal other than the European Journal 22 of Cancer Research? 23 A. No. I don't have any 24 knowledge of it.</p>	<p>1 MR. HUDSON: Objection to 2 form. 3 MR. HEGARTY: Objection to 4 form. 5 THE WITNESS: Can you repeat 6 the question? 7 BY MR. TISI: 8 Q. Yes. The Citizen's Petition 9 was subject to -- it was a collaborative 10 process between yourselves -- 11 A. The response to the 12 Citizen's Petition. 13 Q. The response to the 14 Citizen's Petition -- 15 A. Okay. 16 Q. -- was a collaborative 17 effort between yourselves, Huncharek and 18 Muscat, and Johnson &amp; Johnson and others 19 in the talc industry? 20 MR. HUDSON: Objection to 21 form. 22 THE WITNESS: No. 23 BY MR. TISI: 24 Q. You didn't -- didn't you go</p>
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<p>1 Q. Now, we talked about the 2 financial disclosures, the 3 acknowledgments at the end. I'm going to 4 ask you to assume for me that if you go 5 back and look at the wording of this 6 paper, it is lifted almost verbatim from 7 the Citizen's Petition, because we don't 8 have time to sit here and go paragraph by 9 paragraph, but it is almost verbatim. 10 The Citizen's Petition was a 11 collaborative effort, correct? 12 MR. HUDSON: Objection to 13 form. Counsel's statements. 14 THE WITNESS: So as I said, 15 I did submit graphs for that. 16 That's correct. 17 BY MR. TISI: 18 Q. No, but the Citizen's 19 Petition itself, moving backwards in 20 time, was a collaborative effort between 21 Johnson &amp; Johnson, Imerys, and Huncharek 22 and Muscat. You had meetings. You 23 exchanged drafts. There were edits back 24 and forth. Do you know that to be true?</p>	<p>1 to a meeting and -- 2 A. We went to a meeting. 3 That's correct. 4 Q. And you went through the 5 paper? 6 MR. HEGARTY: Objection to 7 form. 8 THE WITNESS: I'm sorry. 9 Which paper? 10 BY MR. TISI: 11 Q. You went through the report, 12 the response to the Citizen's Petition, 13 correct? 14 A. I don't remember what went 15 on at that meeting. I have no knowledge 16 of the content of that meeting. 17 Q. All right. Do you know 18 whether or not Lorena Telofski -- do you 19 know who she is? 20 A. No. 21 Q. Do you know whether or not 22 anybody from the -- here is a copy of the 23 Exhibit 25, which is a copy -- 26. I'm 24 sorry.</p>

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<p style="text-align: right;">Page 362</p> <p>1 (Document marked for 2 identification as Exhibit 3 Muscat-26.) 4 BY MR. TISI: 5 Q. This is a copy of the 6 Citizen's Petition draft that was sent to 7 you -- that was circulated with edits. 8 Do you see that? 9 MR. HEGARTY: Objection to 10 form. 11 Do you have copies of that, 12 Counsel? 13 MR. TISI: I'm sorry. 14 BY MR. TISI: 15 Q. Do you see that there are 16 notes and meetings -- minute -- reviews 17 of it? 18 MR. HEGARTY: Objection to 19 form. 20 THE WITNESS: I'm sorry. 21 What am I supposed to be looking 22 at? 23 BY MR. TISI: 24 Q. I'm just saying, do you see</p>	<p style="text-align: right;">Page 364</p> <p>1 MR. HUDSON: Objection to 2 form. 3 BY MR. TISI: 4 Q. Before it was submitted to 5 the FDA? 6 A. There was a meeting at J&amp;J 7 that I went to. That is correct. 8 Q. And while you may not 9 remember the specifics, the purpose was 10 to vet this particular report? 11 MR. HUDSON: Objection to 12 form. 13 BY MR. TISI: 14 Q. Do you remember that? 15 A. No. 16 (Document marked for 17 identification as Exhibit 18 Muscat-27.) 19 BY MR. TISI: 20 Q. I'm going to show you what 21 I'd like to have marked as Exhibit 27. 22 Let me identify it. It's an 23 e-mail, November 14, 2008. It says, 24 "Here is the report that Muscat and</p>
<p style="text-align: right;">Page 363</p> <p>1 that there are notes and edits on the 2 document? 3 MR. HEGARTY: Objection to 4 form. 5 THE WITNESS: I don't see 6 any notes. I see that there are 7 track changes. 8 BY MR. TISI: 9 Q. Right. I'm going to 10 represent to you that in the documents 11 that have been provided to us, that the 12 track changes come from Lorena Telofski 13 at J&amp;J. 14 MR. HUDSON: Objection to 15 form. There's no question 16 pending. 17 MR. TISI: I'm about ready 18 to ask it. 19 BY MR. TISI: 20 Q. There was a meeting in 21 November of 2009 to -- 2008 to discuss 22 this report with J&amp;J, correct? 23 MR. HEGARTY: Objection to 24 form.</p>	<p style="text-align: right;">Page 365</p> <p>1 Huncharek have prepared for us to submit 2 to the docket. We will discuss it with 3 them next Wednesday p.m." 4 Do you see that? 5 A. Yes. 6 Q. Okay. So does that refresh 7 your recollection that you discussed this 8 paper with the folks at J&amp;J? 9 MR. HEGARTY: Objection to 10 form. 11 THE WITNESS: Not -- I don't 12 remember any of the details of 13 that day. 14 BY MR. TISI: 15 Q. I didn't ask you if you 16 remember the details. 17 A. Yeah. Okay. 18 Q. Okay. So -- 19 A. I remember being there. 20 Q. And you remember the focus 21 of the meeting was to discuss the 22 contents of the paper that you had 23 prepared for responding to the Citizen's 24 Petition asking that talc contain a</p>



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<p>1 warning of ovarian cancer?</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 MR. HUDSON: Objection to</p> <p>5 form.</p> <p>6 THE WITNESS: So I can only</p> <p>7 tell you what I remember, which is</p> <p>8 that I don't remember that.</p> <p>9 BY MR. TISI:</p> <p>10 Q. It also says, "In addition</p> <p>11 we will discuss the possibility of</p> <p>12 additional work to support long-term</p> <p>13 goals for talc."</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. Did you remember that?</p> <p>17 A. No.</p> <p>18 Q. "Take a look and be prepared</p> <p>19 to discuss your point of view of this</p> <p>20 paper when they're here."</p> <p>21 Correct? Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. Does that refresh</p> <p>24 your recollection that the whole purpose</p>	<p>1 paper that was drafted in response</p> <p>2 to the Citizen's Petition.</p> <p>3 BY MR. TISI:</p> <p>4 Q. Look at the cover page of</p> <p>5 the -- of the draft that I just</p> <p>6 circulated to you. It says, "Prepared</p> <p>7 for J&amp;J," does it not?</p> <p>8 A. Yes, I see that.</p> <p>9 Q. Okay. It was prepared for</p> <p>10 J&amp;J, was it not?</p> <p>11 A. Yes.</p> <p>12 MR. HUDSON: Objection to</p> <p>13 form.</p> <p>14 MR. HEGARTY: Objection.</p> <p>15 BY MR. TISI:</p> <p>16 Q. Okay. And the authorship</p> <p>17 was -- the paper was submitted not on</p> <p>18 behalf of J&amp;J, it was actually submitted</p> <p>19 by PCPC, correct?</p> <p>20 MR. HEGARTY: Objection.</p> <p>21 BY MR. TISI:</p> <p>22 Q. If you look at the final one</p> <p>23 that I gave you, which was Exhibit 25,</p> <p>24 submitted under PCPC, right?</p>
Page 367	Page 369
<p>1 of the meeting was to discuss aspects of</p> <p>2 the paper that you -- that you and</p> <p>3 Dr. Huncharek had drafted?</p> <p>4 MR. HEGARTY: Objection to</p> <p>5 form.</p> <p>6 THE WITNESS: So, no.</p> <p>7 BY MR. TISI:</p> <p>8 Q. Okay. It also says, "We</p> <p>9 have discussed having an interested party</p> <p>10 support the work through the trade</p> <p>11 organization and have them submit it."</p> <p>12 A. No.</p> <p>13 Q. But this was actually a J&amp;J</p> <p>14 paper, right?</p> <p>15 MR. HUDSON: Objection to</p> <p>16 form.</p> <p>17 BY MR. TISI:</p> <p>18 Q. This was a paper that was</p> <p>19 actually drafted for J&amp;J?</p> <p>20 MR. HUDSON: Objection to</p> <p>21 form.</p> <p>22 MR. HEGARTY: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: This was a</p>	<p>1 A. That's correct.</p> <p>2 Q. So the draft was done, it</p> <p>3 was a J&amp;J report, but it was submitted on</p> <p>4 behalf of the entire industry under the</p> <p>5 PCPC letterhead?</p> <p>6 A. I see that, yes.</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Is the European Journal of</p> <p>11 Cancer Prevention a high impact journal?</p> <p>12 Would you consider it a high impact</p> <p>13 journal?</p> <p>14 A. So I don't know what the</p> <p>15 impact factor is.</p> <p>16 Q. It's a relatively low impact</p> <p>17 journal. It's not one that everybody</p> <p>18 reads, is it?</p> <p>19 MR. HUDSON: Objection to</p> <p>20 form.</p> <p>21 MR. HEGARTY: Objection to</p> <p>22 form.</p> <p>23 BY MR. TISI:</p> <p>24 Q. It's not a widely cited</p>



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<p style="text-align: right;">Page 370</p> <p>1 journal, is it?</p> <p>2 A. It's probably not. It's a</p> <p>3 specialty journal.</p> <p>4 Q. Now, the acknowledgment</p> <p>5 says, "Dr. Muscat and Huncharek" -- the</p> <p>6 acknowledgment to the 2011 article, it</p> <p>7 says, "Dr. Huncharek and Muscat were</p> <p>8 consultants to Johnson &amp; Johnson and</p> <p>9 Consumer Products Worldwide at the time</p> <p>10 the initial drafts of this manuscript</p> <p>11 were produced."</p> <p>12 Correct?</p> <p>13 A. Yes.</p> <p>14 Q. But you were also</p> <p>15 consultants at the time the manuscript</p> <p>16 was submitted, correct?</p> <p>17 MR. HEGARTY: Objection to</p> <p>18 form.</p> <p>19 THE WITNESS: That, I can't</p> <p>20 answer.</p> <p>21 BY MR. TISI:</p> <p>22 Q. You were consultants -- this</p> <p>23 was submitted in April 2011. You were</p> <p>24 not only just consultants, you were</p>	<p style="text-align: right;">Page 372</p> <p>1 published as well, right?</p> <p>2 A. It was at the time the</p> <p>3 initial drafts were produced. I assume</p> <p>4 that means produced and submitted at the</p> <p>5 same time. I don't see that distinction.</p> <p>6 Q. I know you don't.</p> <p>7 A. Yeah.</p> <p>8 Q. But other people might.</p> <p>9 The question is --</p> <p>10 A. That's -- I don't understand</p> <p>11 what the --</p> <p>12 Q. You were also litigation</p> <p>13 consultants at the time that it was</p> <p>14 submitted, correct?</p> <p>15 MR. HEGARTY: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: The -- I</p> <p>18 started my work with Shook Hardy &amp;</p> <p>19 Bacon in 2010; that's correct.</p> <p>20 BY MR. TISI:</p> <p>21 Q. When you say you started</p> <p>22 your work, you mean as a litigation</p> <p>23 expert?</p> <p>24 A. That's correct.</p>
<p style="text-align: right;">Page 371</p> <p>1 experts.</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Fair?</p> <p>6 A. I'm sorry. With regard to</p> <p>7 what?</p> <p>8 Q. For Johnson &amp; Johnson and --</p> <p>9 you were an -- you were an expert for</p> <p>10 Johnson &amp; Johnson in 2011 when this was</p> <p>11 submitted.</p> <p>12 A. So I thought we went over</p> <p>13 this. So first of all, Dr. Huncharek</p> <p>14 wrote that. So I'm not responsible for</p> <p>15 the specific wording. But it says,</p> <p>16 "Dr. Huncharek and Muscat were</p> <p>17 consultants to Johnson &amp; Johnson Consumer</p> <p>18 Product Worldwide."</p> <p>19 Q. Finish the sentence, please.</p> <p>20 A. "At the time the initial</p> <p>21 drafts of this manuscript was produced."</p> <p>22 Q. Okay. But you were also</p> <p>23 consultants at the time that it was</p> <p>24 submitted and at the time that it was</p>	<p style="text-align: right;">Page 373</p> <p>1 Q. And did you acknowledge any</p> <p>2 contribution that anybody at Johnson &amp;</p> <p>3 Johnson made to the underlying paper?</p> <p>4 MR. HEGARTY: Objection to</p> <p>5 form.</p> <p>6 THE WITNESS: To my</p> <p>7 knowledge, they didn't make any</p> <p>8 contribution.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Okay. But that would be a</p> <p>11 question for Dr. Huncharek, I guess,</p> <p>12 right?</p> <p>13 A. That's correct.</p> <p>14 Q. All right. Let's go to your</p> <p>15 second journal here. The Critical Review</p> <p>16 from 19 -- 2008.</p> <p>17 (Document marked for</p> <p>18 identification as Exhibit</p> <p>19 Muscat-28.)</p> <p>20 BY MR. TISI:</p> <p>21 Q. This is Exhibit Number 28.</p> <p>22 This was also published in the European</p> <p>23 Journal of Cancer Prevention.</p> <p>24 A. That's correct.</p>



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<p style="text-align: right;">Page 374</p> <p>1 Q. It was accepted for 2 publication in April of 2008, correct? 3 A. That's correct. 4 Q. But this wasn't the first 5 journal that it was submitted to. We 6 talked about that before, correct? 7 A. That's correct. 8 Q. It was submitted to 9 Environmental Health Perspectives in 10 January of 2006. 11 Did you know that? 12 A. I don't have the exact date. 13 Q. That was correct, right? 14 They rejected it. 15 A. They rejected it. 16 Q. It was submitted to the 17 journal called Gynecology Oncology in 18 March of 2006, and they rejected it as 19 well, correct? 20 MR. HUDSON: Objection to 21 form. 22 MR. HEGARTY: Objection to 23 form. 24 THE WITNESS: I don't</p>	<p style="text-align: right;">Page 376</p> <p>1 A. It ultimately was rejected. 2 Q. By the Clinical Epidemiology 3 journal, correct? 4 A. I believe it was called the 5 Journal of Clinical Epidemiology. 6 Q. And it was submitted to The 7 Lancet? 8 A. No. 9 Q. It was not submitted to The 10 Lancet? 11 A. No. 12 Q. So this journal was the 13 journal, the European Journal of -- 14 A. -- Cancer Prevention. 15 Q. -- Cancer Prevention was not 16 your first choice, was it? 17 MR. HUDSON: Objection to 18 form. 19 THE WITNESS: It was not the 20 first journal that I submitted it 21 to. 22 BY MR. TISI: 23 Q. And it was -- this again, is 24 a low impact journal, correct?</p>
<p style="text-align: right;">Page 375</p> <p>1 remember if it was actually ever 2 submitted there. 3 BY MR. TISI: 4 Q. Okay. Do you think it was? 5 A. I don't recall. 6 Q. It was submitted to the 7 Journal of Clinical Epidemiology in March 8 of 2006? 9 A. It was submitted. I don't 10 recall the exact date. 11 Q. It was rejected by them as 12 well? 13 A. No, not initially. 14 Initially it was invited to be 15 resubmitted with revisions. 16 Q. And you don't like the 17 revisions, so you withdrew it and 18 submitted elsewhere, right? 19 MR. HUDSON: Objection to 20 form. 21 THE WITNESS: No. We made 22 revisions on the paper. 23 BY MR. TISI: 24 Q. And then it was rejected?</p>	<p style="text-align: right;">Page 377</p> <p>1 MR. HEGARTY: Objection to 2 form. 3 THE WITNESS: I don't know 4 what the impact factor is. When 5 you're submitting to a journal, 6 you're trying to find a journal 7 that has a topic area that would 8 have an interest in the article. 9 BY MR. TISI: 10 Q. Now, in Section -- go to 11 Page 505 if you would of that article. 12 And there's a whole section 13 here -- 14 MR. HEGARTY: Which page? 15 I'm sorry. 16 MR. TISI: I'm sorry. I'm 17 looking at the wrong one. Can you 18 give me my copy back -- a copy to 19 me back? Thank you, Counsel. 20 BY MR. TISI: 21 Q. There's a whole section in 22 here on asbestos contamination and 23 confounding on Page 142. 24 Do you see that?</p>

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<p style="text-align: right;">Page 378</p> <p>1 A. Yes.</p> <p>2 Q. Do you remember I talked to</p> <p>3 you before about questions relating to</p> <p>4 mineralogy and structural similarities</p> <p>5 between asbestos and talc. Do you</p> <p>6 remember that?</p> <p>7 A. Yes.</p> <p>8 MR. HEGARTY: Objection to</p> <p>9 form.</p> <p>10 BY MR. TISI:</p> <p>11 Q. And the question is, did you</p> <p>12 have any mineralogist or anybody who</p> <p>13 looked at this paper in order to -- to</p> <p>14 your knowledge -- first of all, let me</p> <p>15 ask the question before we go any</p> <p>16 further.</p> <p>17 Is this another article that</p> <p>18 was basically written by Dr. Huncharek?</p> <p>19 A. No, it wasn't.</p> <p>20 Q. You wrote this one?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Did you consult with</p> <p>23 any mineralogist or geologist about</p> <p>24 issues relating to the structure of talc?</p>	<p style="text-align: right;">Page 380</p> <p>1 A. Yeah, I see that.</p> <p>2 Q. Okay. And the Rohl 1976</p> <p>3 refers to the second part of that</p> <p>4 sentence, meaning that some baby powders</p> <p>5 manufactured in the '70s contained small</p> <p>6 amounts of tremolite or quartz, right?</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: I can't say</p> <p>10 without looking whether it refers</p> <p>11 to the whole sentence or the</p> <p>12 second part of the sentence.</p> <p>13 BY MR. TISI:</p> <p>14 Q. Well, if you know the</p> <p>15 article was 1976, you know that it wasn't</p> <p>16 referring to recent -- talc that was</p> <p>17 manufactured and distributed from 1976</p> <p>18 forward, right?</p> <p>19 MR. HEGARTY: Objection to</p> <p>20 form.</p> <p>21 THE WITNESS: I'm sorry.</p> <p>22 What was that?</p> <p>23 BY MR. TISI:</p> <p>24 Q. If the article was written</p>
<p style="text-align: right;">Page 379</p> <p>1 A. No.</p> <p>2 Q. Okay. And here, it talks</p> <p>3 about -- so if you go to Page 142, it</p> <p>4 says -- this is the example of what I was</p> <p>5 talking about. "Cosmetic talcum powder</p> <p>6 contains greater than 99 pure" -- "95 to</p> <p>7 99 percent pure talc" -- "pure talc,</p> <p>8 whereas other dusting powders are</p> <p>9 typically composed of talc, cornstarch,</p> <p>10 and other additives."</p> <p>11 Do you see that, right?</p> <p>12 A. I'm sorry. Where is it?</p> <p>13 Q. On Page 142. Do you see</p> <p>14 that?</p> <p>15 A. Yes.</p> <p>16 Q. Now, the next sentence is</p> <p>17 kind of one of the examples that I was</p> <p>18 talking about before. It says, "Cosmetic</p> <p>19 grade talc is asbestos free and has been</p> <p>20 for several decades, but some baby</p> <p>21 powders manufactured in 1970s contained a</p> <p>22 small amount of tremolite or quartz</p> <p>23 silica." And then says Rohl 1976,</p> <p>24 correct?</p>	<p style="text-align: right;">Page 381</p> <p>1 in 1976 --</p> <p>2 A. Yes.</p> <p>3 Q. -- it does not refer to</p> <p>4 talc --</p> <p>5 A. Yes.</p> <p>6 Q. -- manufactured between</p> <p>7 1976 --</p> <p>8 A. Yes.</p> <p>9 Q. -- and the date the article</p> <p>10 was written --</p> <p>11 A. Yes, that's correct.</p> <p>12 Q. -- and submitted in 2008,</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. There's nothing cited in</p> <p>16 this article saying that talc was</p> <p>17 asbestos free in the 1980s, 1990s and</p> <p>18 2000s, is there?</p> <p>19 A. In this article, that's</p> <p>20 correct.</p> <p>21 Q. Is there any place that you</p> <p>22 can ever remember citing that -- for the</p> <p>23 proposition that talc is -- that talcum</p> <p>24 powder products are asbestos free, or did</p>



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<p>1 you get that from someplace?</p> <p>2 A. So that --</p> <p>3 MR. HEGARTY: Objection to</p> <p>4 form.</p> <p>5 THE WITNESS: That just came</p> <p>6 from sort of my general</p> <p>7 understanding from the IARC</p> <p>8 monograph at the -- it's been</p> <p>9 asbestos free.</p> <p>10 BY MR. TISI:</p> <p>11 Q. You didn't cite IARC</p> <p>12 monograph here, did you?</p> <p>13 A. I didn't cite it.</p> <p>14 Q. Okay. So I really want to</p> <p>15 know other than this general idea that</p> <p>16 you have -- and this is one of those</p> <p>17 examples that I talked about before.</p> <p>18 Other than a general idea, are there any</p> <p>19 place that you can cite to me where there</p> <p>20 was a survey done or some testing done of</p> <p>21 talc or talcum powder products which</p> <p>22 demonstrates that, and to use your words,</p> <p>23 "Cosmetic grade talc is asbestos free and</p> <p>24 has been for decades"?</p>	<p>1 BY MR. TISI:</p> <p>2 Q. Okay. So my question is,</p> <p>3 the grade that is used in Johnson &amp;</p> <p>4 Johnson's Baby Powder or Shower to Shower</p> <p>5 products, you really don't know whether</p> <p>6 or not it is, to use your words,</p> <p>7 asbestos-free and has been for several</p> <p>8 decades. You don't know that, do you?</p> <p>9 MR. HEGARTY: Objection to</p> <p>10 form.</p> <p>11 THE WITNESS: So my</p> <p>12 assumption based on the literature</p> <p>13 is that it has been. I've never</p> <p>14 seen anything that actually says</p> <p>15 that it is.</p> <p>16 BY MR. TISI:</p> <p>17 Q. Right. One way or the</p> <p>18 other, right?</p> <p>19 MR. HEGARTY: Objection to</p> <p>20 form.</p> <p>21 THE WITNESS: All I can say</p> <p>22 is that, in general discussions</p> <p>23 and being at the -- you know, with</p> <p>24 the IARC monograph, I don't --</p>
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<p>1 MR. HEGARTY: Objection to</p> <p>2 form.</p> <p>3 THE WITNESS: So there have</p> <p>4 been studies that have been done</p> <p>5 in miners where they did analyses</p> <p>6 for talc and for European mines</p> <p>7 and in Vermont.</p> <p>8 BY MR. TISI:</p> <p>9 Q. But those aren't talcum</p> <p>10 powder products, are they?</p> <p>11 A. They are mines that are --</p> <p>12 where talcum powder products come from.</p> <p>13 Q. Right. I'm talking about</p> <p>14 survey -- talcum powder products, do they</p> <p>15 go through a manufacturing process,</p> <p>16 right?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. So certain grades of</p> <p>19 talc make it, certain don't, correct? Or</p> <p>20 you don't know that?</p> <p>21 MR. HEGARTY: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: The talcum</p> <p>24 powder is a pure grade, yes.</p>	<p>1 I've never come across an argument</p> <p>2 that there's asbestos particles in</p> <p>3 cosmetic grade talc powder.</p> <p>4 BY MR. TISI:</p> <p>5 Q. The discussions that you had</p> <p>6 were people like John Hopkins at</p> <p>7 Johnson &amp; Johnson, correct?</p> <p>8 MR. HEGARTY: Objection to</p> <p>9 form.</p> <p>10 THE WITNESS: No.</p> <p>11 BY MR. TISI:</p> <p>12 Q. You have spoken to John</p> <p>13 Hopkins, right?</p> <p>14 A. Many years ago.</p> <p>15 Q. Okay. Did you submit a --</p> <p>16 now this one has an acknowledgment,</p> <p>17 Exhibit 28, has an acknowledgment section</p> <p>18 too. Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. It says, this was</p> <p>21 supported -- this one was supported by a</p> <p>22 contract from Crowell &amp; Moring, Inc.</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p>



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<p>1 Q. First of all, Crowell &amp; 2 Moring is not -- it's a law firm. It's 3 not an Inc.? 4 MR. SILVER: Objection to 5 form. 6 MR. HEGARTY: Objection to 7 form. 8 BY MR. TISI: 9 Q. It's not a company, is it? 10 It's a law firm? 11 MR. SILVER: Objection to 12 form. 13 THE WITNESS: It's a law 14 firm. 15 BY MR. TISI: 16 Q. Okay. And it doesn't 17 acknowledge any involvement -- now, the 18 contract with Crowell &amp; Moring, Inc., was 19 for the benefit of Johnson &amp; Johnson and 20 Imerys, correct? 21 MR. HEGARTY: Objection to 22 form. 23 THE WITNESS: I understand 24 that -- now that was the case.</p>	<p>1 understand the question. Can you 2 repeat it? 3 BY MR. TISI: 4 Q. Yes. Do you think anybody 5 realistically reading this article would 6 realize that this article was supported 7 by a contract with a law firm? 8 MR. SILVER: Objection to 9 form. 10 MR. HUDSON: Objection to 11 form. 12 THE WITNESS: It's supported 13 by a law firm. That's correct. I 14 stated that. 15 BY MR. TISI: 16 Q. Do you think anybody would 17 ever know that Crowell &amp; Moring is a law 18 firm? 19 MR. HUDSON: Objection to 20 form. 21 MR. SILVER: Objection to 22 form. 23 THE WITNESS: Maybe they 24 would, yeah.</p>
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<p>1 BY MR. TISI: 2 Q. They're not disclosed in 3 this article, are they? 4 A. That's correct. 5 Q. You wouldn't blame anybody 6 for looking at this article and not 7 understanding that Crowell &amp; Moring was 8 the law firm representing Imerys in this 9 matter, do you? 10 MR. SILVER: Objection to 11 form. 12 MR. HEGARTY: Objection. 13 THE WITNESS: I'm sorry. 14 Can you repeat that? 15 BY MR. TISI: 16 Q. Would you blame any reader 17 of this article for not knowing that this 18 is written pursuant to a contract with a 19 law firm? 20 MR. HUDSON: Objection to 21 form. 22 MR. SILVER: Objection to 23 form. 24 THE WITNESS: I still don't</p>	<p>1 MR. TISI: Well, let me -- 2 let me -- 3 THE WITNESS: Yeah. 4 MR. TISI: Can you just play 5 clip one, please. This is from 6 the deposition -- 7 BY MR. TISI: 8 Q. You know who Susan Nicholson 9 is, don't you? You spoke to 10 Dr. Nicholson. She called you about 11 this? 12 A. Yes, right. 13 Q. And Susan Nicholson works 14 for Johnson &amp; Johnson, right? 15 A. Yes. 16 Q. Okay. And Susan Nicholson 17 is like the highest levels of Johnson &amp; 18 Johnson, correct? 19 MR. SILVER: Objection to 20 form. 21 MR. HUDSON: Objection to 22 form. 23 THE WITNESS: I don't know 24 her personally.</p>

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<p>1 BY MR. TISI:</p> <p>2 Q. She's a chief medical --</p> <p>3 she's a chief medical officer or</p> <p>4 something like that?</p> <p>5 MR. HEGARTY: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: I don't know</p> <p>8 her title.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Well, I'll tell you she was</p> <p>11 produced to us as a witness representing</p> <p>12 the company and speaking for Johnson &amp;</p> <p>13 Johnson?</p> <p>14 A. Okay.</p> <p>15 MR. HEGARTY: Objection to</p> <p>16 form.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Let me show you what she</p> <p>19 said about Crowell &amp; Moring.</p> <p>20 (Video playback.)</p> <p>21 MR. TISI: The contract from</p> <p>22 Crowell &amp; Moring, Inc., before you</p> <p>23 came in here and you had read this</p> <p>24 article, would you have any idea</p>	<p>1 Q. Okay. And it doesn't</p> <p>2 mention J&amp;J, right?</p> <p>3 A. It mentions Crowell &amp;</p> <p>4 Moring.</p> <p>5 Q. It doesn't mention J&amp;J?</p> <p>6 A. No, it doesn't.</p> <p>7 Q. It doesn't mention Imerys?</p> <p>8 A. No, it doesn't.</p> <p>9 Q. Does it mention -- do you</p> <p>10 give any -- it gives an acknowledgment to</p> <p>11 Lamar Wheeler. Who's Lamar Wheeler?</p> <p>12 A. That's the spouse of</p> <p>13 Dr. Huncharek.</p> <p>14 Q. Okay. It doesn't give any</p> <p>15 acknowledgment to Ridge Hall, right, who</p> <p>16 was one of the lawyers who kind of red</p> <p>17 lined a prior version of this paper,</p> <p>18 right?</p> <p>19 MR. SILVER: Objection to</p> <p>20 form.</p> <p>21 MR. HEGARTY: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: No, he didn't</p> <p>24 red line a prior version of this</p>
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<p>1 of knowing Crowell &amp; Moring, Inc.,</p> <p>2 was a law firm?</p> <p>3 MR. NICHOLSON: No, I would</p> <p>4 not.</p> <p>5 (End of video playback.)</p> <p>6 BY MR. TISI:</p> <p>7 Q. Do you have any -- do you</p> <p>8 have any reason to believe that any</p> <p>9 person looking at this article</p> <p>10 objectively would know this was written</p> <p>11 under a contract with a law firm?</p> <p>12 MR. SILVER: Objection to</p> <p>13 form.</p> <p>14 MR. HEGARTY: Objection to</p> <p>15 form. Asked and answered.</p> <p>16 MR. HUDSON: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: If anybody had</p> <p>19 a question to that, they could</p> <p>20 have called me, and I would</p> <p>21 explain it's a law firm.</p> <p>22 But I don't see what the</p> <p>23 issue is though.</p> <p>24 BY MR. TISI:</p>	<p>1 paper. He had nothing to do with</p> <p>2 it.</p> <p>3 BY MR. TISI:</p> <p>4 Q. Nothing to do with it?</p> <p>5 A. Nothing.</p> <p>6 Q. Absolutely nothing?</p> <p>7 A. Nothing.</p> <p>8 Q. Okay. And how about</p> <p>9 Dr. McCarthy?</p> <p>10 A. With this paper?</p> <p>11 Q. Yeah.</p> <p>12 A. Nothing.</p> <p>13 Q. Dr. Glenn?</p> <p>14 A. Nothing.</p> <p>15 Q. Nothing whatsoever?</p> <p>16 A. Nothing.</p> <p>17 Q. Absolutely zero?</p> <p>18 A. Absolutely zero, nothing.</p> <p>19 Q. And if I took the drafts of</p> <p>20 the article that was submitted in 2005</p> <p>21 and compared it to the final paper, there</p> <p>22 would be absolutely nothing in common?</p> <p>23 MR. SILVER: Objection to</p> <p>24 form.</p>

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<p>1 MR. HUDSON: Objection to 2 form. 3 THE WITNESS: They are 4 almost entirely different 5 articles. 6 BY MR. TISI: 7 Q. Okay. 8 A. Okay. So. 9 (Document marked for 10 identification as Exhibit 11 Muscat-29.) 12 BY MR. TISI: 13 Q. I'm going to show you what 14 I'd like to have marked as Exhibit 15 Number -- could you please put the prior 16 article up on this one as well. 17 Now, this, Doctor, is a 18 draft of an article, this is an article, 19 "Perineal Talc Use, and Ovarian Cancer: 20 A Critical Review." 21 Do you see that? Do you see 22 that? 23 A. I'm sorry. Which one are 24 you referring to?</p>	<p>1 BY MR. TISI: 2 Q. Do you see that? 3 MR. HEGARTY: Objection. No 4 question. 5 BY MR. TISI: 6 Q. Yeah. Do you see that says 7 Tim McCarthy? 8 A. Oh, I'm sorry. 9 MR. HEGARTY: Objection to 10 form. 11 BY MR. TISI: 12 Q. Do you see that? 13 A. Oh, okay. On the front 14 page? 15 Q. Mm-hmm. And do you see that 16 this is in fact the same title or similar 17 title, "Perineal Talc Use and Ovarian 18 Cancer: A Critical Review." And the 19 earlier versions an edited version of 20 this by Tim McCarthy? 21 MR. HUDSON: Objection to 22 form. 23 THE WITNESS: It's a 24 different title. It's not the</p>
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<p>1 Q. Oh, okay. 2 A. "Talc and Ovarian Cancer." 3 Yes. 4 Q. Do you see that this is, to 5 the left, is an article -- is a draft of 6 an article entitled "Talc and Cancer: A 7 Critical Review." A report to Crowell &amp; 8 Moring by Michael Huncharek and Joshua 9 Muscat. 10 Do you see that? 11 A. Yes. 12 Q. And do you see the first 13 page of that is a cover sheet, and I 14 pulled it from the documents that have 15 been produced to us. And it's 16 entitled -- it's a draft that was edited 17 by Tim McCarthy. You know who Tim 18 McCarthy was, right? 19 MR. HEGARTY: Objection to 20 form. 21 MR. HUDSON: Objection to 22 form. 23 MR. SILVER: Objection to 24 form.</p>	<p>1 same version. This is a different 2 product. 3 BY MR. TISI: 4 Q. Okay. We'll see. All 5 right. Let's go to the next one, your 6 diaphragm meta-analysis. Exhibit 30. 7 This is part of your binder, but I'm 8 going to mark it as 30. 9 (Document marked for 10 identification as Exhibit 11 Muscat-30.) 12 BY MR. TISI: 13 Q. Diaphragm published 14 meta-analysis. 15 A. Yes. 16 Q. Again, this is in the very 17 same journal that we talked with the last 18 two articles, the European Journal of 19 Cancer Prevention? 20 A. Yes. 21 Q. It's a third article 22 produced in this journal on this issue, 23 correct? 24 A. That's correct.</p>



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<p>1 MR. HUDSON: Objection to 2 form. 3 MR. HEGARTY: Objection to 4 form. 5 BY MR. TISI: 6 Q. This is really your go-to 7 journal for talc, wasn't it? 8 MR. SILVER: Objection to 9 form. 10 MR. HEGARTY: Objection to 11 form. 12 THE WITNESS: So this is, 13 like, cancer prevention. So it's 14 an appropriate journal for -- 15 BY MR. TISI: 16 Q. I didn't ask you that. I 17 asked you, was this article submitted and 18 rejected by another journal as well? 19 MR. HUDSON: Objection to 20 form. 21 THE WITNESS: I have -- I 22 have no knowledge of that. 23 BY MR. TISI: 24 Q. You have no knowledge of</p>	<p>1 doubt on the talc that was dusted on a 2 woman more remotely from the ovaries, 3 correct? 4 MR. HEGARTY: Objection to 5 form. 6 THE WITNESS: I would say 7 it's a -- it's a better test to 8 the hypothesis. 9 BY MR. TISI: 10 Q. "And therefore, the present 11 data describes a result of a 12 meta-analysis pooling data from 13 epidemiology studies examining the risk 14 of women of ovarian cancer associated 15 with the use of cosmetic talc on 16 diaphragms." 17 A. Yeah. 18 Q. Okay. We're going to talk 19 about this later. But the premise of 20 this article is to focus solely on 21 diaphragms that are dusted with talc? 22 A. That's correct. 23 Q. And so if this study 24 contains -- contains diaphragms that were</p>
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<p>1 that? 2 A. That's correct. 3 Q. Dr. -- would -- 4 Dr. Huncharek would know that, right? 5 A. That's correct. 6 Q. Now, the purpose of this 7 article, as best as I understand it, is 8 to say that your assumption -- the 9 hypothesis was -- and if you go on Page 10 2, you have the -- there's a paragraph on 11 the left that says, "It appears, however, 12 that talc ovarian cancer hypothesis could 13 be tested with better precision and 14 validity if the exposure to the suspected 15 carcinogen was directed to the 16 reproductive tract." Correct? 17 A. I see that, yes. 18 Q. And that was the hypothesis 19 that you thought was a good idea to test? 20 A. Yes. 21 Q. Okay. In other words, if 22 talc was closer to the ovaries through 23 use of a diaphragm, and did not show an 24 increased risk; therefore, it would cast</p>	<p>1 either not dusted with talc or that did 2 not have -- that wasn't including 3 diaphragms at all, that would be -- that 4 would be inappropriate to include in this 5 study? 6 A. I think all the data that 7 was cited were studies of talc-dusted 8 diaphragms. 9 Q. We are going to talk about 10 that very issue. 11 A. Okay. 12 Q. We will. But that was the 13 hypothesis that you were testing here, 14 right? 15 A. Yes. 16 Q. And this one, the 17 acknowledgment in the end, it says this 18 one was work provided by a grant from 19 Luzenac America -- American, Inc., and 20 Johnson &amp; Johnson Consumer Products 21 Worldwide, right? 22 MR. SILVER: Objection to 23 form. 24 BY MR. TISI:</p>



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<p>1 Q. Do you see that?</p> <p>2 A. I see that.</p> <p>3 Q. Now, this one talks about a</p> <p>4 grant, and we talked about before, this</p> <p>5 was under a contract. This wasn't a</p> <p>6 grant.</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: That would</p> <p>10 better describe it.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Okay. And this one doesn't</p> <p>13 acknowledge any contribution, where the</p> <p>14 other one talked about Crowell &amp; Moring</p> <p>15 Inc., this one doesn't mention Crowell &amp;</p> <p>16 Moring at all?</p> <p>17 A. That's correct.</p> <p>18 Q. Okay. But this one was</p> <p>19 drafted under the contract with Crowell &amp;</p> <p>20 Moring, as well?</p> <p>21 MR. HEGARTY: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: I believe so.</p> <p>24 BY MR. TISI:</p>	<p>1 Q. Okay. That's an</p> <p>2 unreasonable to thing to expect somebody</p> <p>3 to do, huh?</p> <p>4 MR. SILVER: Objection to</p> <p>5 form.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Right? Scientists don't do</p> <p>8 that, do they?</p> <p>9 MR. HUDSON: Objection to</p> <p>10 form.</p> <p>11 BY MR. TISI:</p> <p>12 Q. As a matter of course?</p> <p>13 A. What's that?</p> <p>14 Q. Contact and ask and probe</p> <p>15 people about their conflicts of interest?</p> <p>16 A. It -- so I'm not sure what</p> <p>17 the purpose of the -- what are you</p> <p>18 getting at?</p> <p>19 Q. All right. Let's withdraw</p> <p>20 the question.</p> <p>21 A. Okay.</p> <p>22 Q. If we wanted to ask about</p> <p>23 the 2003 meta-analysis, we would have to</p> <p>24 go to Dr. Huncharek?</p>
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<p>1 Q. And there would be no way of</p> <p>2 anybody reading this article knowing that</p> <p>3 this article was drafted under a contract</p> <p>4 with a law firm, correct?</p> <p>5 MR. HEGARTY: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: It's not --</p> <p>8 that's correct.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Okay. And of course, as you</p> <p>11 said before, I guess somebody could have</p> <p>12 called you up and said, "Was this done</p> <p>13 under a contract with a law firm," and</p> <p>14 they might have found that out, right?</p> <p>15 MR. HEGARTY: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: Yes.</p> <p>18 BY MR. TISI:</p> <p>19 Q. You expect -- have you done</p> <p>20 that in all the years that you've been --</p> <p>21 that you've a called up somebody and</p> <p>22 asked what their affiliation is?</p> <p>23 A. Have I ever done that?</p> <p>24 Affiliation. Not that I can recall.</p>	<p>1 A. That's correct.</p> <p>2 Q. Even though you were on the</p> <p>3 original paper, you weren't there. You</p> <p>4 didn't know anything about it.</p> <p>5 A. I didn't.</p> <p>6 Q. Okay. Let's go back to the</p> <p>7 Citizen's. Now I wanted to go to the</p> <p>8 next one, which is the agreed-to</p> <p>9 scientific principles. We're back here.</p> <p>10 We went through publication</p> <p>11 timelines, talc industry funding of</p> <p>12 Muscat studies and regulatory reports.</p> <p>13 Now I want to go to agreed-on scientific</p> <p>14 principles. This is going to be very</p> <p>15 quick because I don't think it's going to</p> <p>16 be really disputed. So let's just go</p> <p>17 through it.</p> <p>18 Can you go to the Citizen's</p> <p>19 Petition in 2011 -- excuse me, 2009.</p> <p>20 PCPC with your report on it. Do you see</p> <p>21 that?</p> <p>22 MR. HEGARTY: What exhibit</p> <p>23 number?</p> <p>24 MR. TISI: Exhibit</p>

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<p style="text-align: right;">Page 406</p> <p>1 Number 25. 2 MR. HEGARTY: Thank you. 3 MR. TISI: You're welcome. 4 BY MR. TISI: 5 Q. Can you go to Page 21 of the 6 document. Okay. Now, this introduction 7 is basic -- it talks about basic -- first 8 of all, have you reviewed this prior to 9 your deposition today? 10 A. I briefly looked at it. 11 Q. Okay. So you talk about 12 some general -- this is the -- I 13 understand that your testimony, that this 14 was primarily written by Dr. Huncharek. 15 A. That's correct. 16 Q. But maybe we can talk about 17 it and I think you can agree to it. 18 It says here, it talks about 19 the general concepts of science and how 20 science develops and how people, 21 epidemiologists do their work. 22 A. Okay. 23 MR. HEGARTY: Objection. 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 408</p> <p>1 human studies, the experimental design 2 has come to represent the gold standard 3 of cause and effect relationships is the 4 randomized clinical trial." 5 Do you see that? 6 You can look here. It may 7 make your life a little easier. 8 A. Okay, I'm sorry. Okay, 9 okay. Yes, I see that. 10 Q. Okay. And that's where you 11 take people prospectively, you randomize 12 them, you give them for example, a drug 13 or not and you see what the effect is, 14 and you give people placebo and you see 15 if there's an effect as well? 16 A. That's correct. 17 Q. Can't do that with, when 18 your hypothesis is does -- does talcum 19 powder products cause cancer, right? 20 A. That's correct. 21 Q. For several reasons. Number 22 one is it would be very unethical to give 23 somebody a product that you think might 24 cause cancer?</p>
<p style="text-align: right;">Page 407</p> <p>1 Q. Okay. And at the very 2 bottom here it says, "In the context of 3 human studies, the experimental design 4 has come to represent the gold standard 5 of cause and effect relationships are 6 randomized clinical trials." 7 Do you see that? 8 MR. HEGARTY: I don't think 9 we are on the same page. 10 THE WITNESS: Page 21 or? 11 MR. HEGARTY: 21 or 29? 12 MR. TISI: Right here. 21. 13 MR. HUDSON: Oh, you mean 21 14 in the top right-hand corner. 15 MR. TISI: Yeah, of the 16 document. 17 MR. HUDSON: We were looking 18 at 21 on the bottom. 19 THE WITNESS: I'm sorry, 20 okay. 21 BY MR. TISI: 22 Q. It says here, let's start in 23 the beginning. I have it on the screen 24 for you. It says, "In the context of</p>	<p style="text-align: right;">Page 409</p> <p>1 MR. HUDSON: Objection to 2 form. 3 MR. HEGARTY: Objection to 4 form. 5 BY MR. TISI: 6 Q. And compare them to people 7 who don't, right? 8 A. So I would disagree with the 9 statement that it causes cancer. 10 Q. I didn't -- 11 A. Okay. 12 Q. As a -- as a general -- 13 A. Okay. 14 Q. Let's at least talk about, 15 if your hypothesis is that this pen, this 16 pen causes cancer, okay, and you want to 17 expose somebody, you want to expose five 18 people to this pen and five people to a 19 different pen that doesn't cause -- you 20 think may not cause cancer, you can't do 21 that study because you don't want to 22 expose people to a -- to a pen that might 23 cause cancer? 24 MR. HEGARTY: Objection to</p>



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<p style="text-align: right;">Page 410</p> <p>1 form.</p> <p>2 THE WITNESS: So can I just</p> <p>3 qualify that?</p> <p>4 BY MR. TISI:</p> <p>5 Q. Yeah.</p> <p>6 A. Okay. You can do like a</p> <p>7 very short-term study. For instance,</p> <p>8 you're interested in the toxicity of a</p> <p>9 particular product and you know that if</p> <p>10 somebody is going to be exposed to it for</p> <p>11 five minutes that it's not going to cause</p> <p>12 cancer. So -- but in general you are</p> <p>13 correct that one has to be careful in</p> <p>14 terms of doing those type of studies that</p> <p>15 involves a potentially toxic exposure.</p> <p>16 Q. So there's no surprise here</p> <p>17 that there's no clinical trials where</p> <p>18 people are exposed to talc and see</p> <p>19 whether or not it causes cancer?</p> <p>20 A. That's correct.</p> <p>21 MR. HEGARTY: Objection.</p> <p>22 BY MR. TISI:</p> <p>23 Q. All right. So -- and that's</p> <p>24 the point that's made next, which is,</p>	<p style="text-align: right;">Page 412</p> <p>1 A. That's correct.</p> <p>2 Q. Like the case-control</p> <p>3 studies that we -- that -- that you</p> <p>4 proposed to Johnson &amp; Johnson and they</p> <p>5 didn't do?</p> <p>6 MR. HEGARTY: Objection to</p> <p>7 form.</p> <p>8 BY MR. TISI:</p> <p>9 Q. Right. Like that?</p> <p>10 A. They didn't do it. They</p> <p>11 didn't fund it.</p> <p>12 Q. But because of that fact</p> <p>13 that you can't study whether talc causes</p> <p>14 cancer directly, you use epidemiologic</p> <p>15 methods, correct --</p> <p>16 MR. HEGARTY: Objection to</p> <p>17 form.</p> <p>18 BY MR. TISI:</p> <p>19 Q. -- to do that, and that's</p> <p>20 what this point says here.</p> <p>21 It says, "Because of that</p> <p>22 fact, criteria for establishing cause and</p> <p>23 effect relationships are inherently</p> <p>24 different when utilizing epidemiologic</p>
<p style="text-align: right;">Page 411</p> <p>1 "Unfortunately in epidemiologic research,</p> <p>2 issues of feasibility and ethical</p> <p>3 considerations preclude those kinds of</p> <p>4 studies."</p> <p>5 A. I see that.</p> <p>6 Q. You see that?</p> <p>7 A. Mm-hmm.</p> <p>8 Q. And that's what -- that's</p> <p>9 what is meant here, right?</p> <p>10 MR. HEGARTY: Objection.</p> <p>11 THE WITNESS: Yes.</p> <p>12 BY MR. TISI:</p> <p>13 Q. All right. So, therefore,</p> <p>14 the epidemiologist must substitute</p> <p>15 observational methods of study to study</p> <p>16 cause and effect relationships that</p> <p>17 preclude direct intervention with or</p> <p>18 manipulation of the study subjects. In</p> <p>19 other words, studies that don't</p> <p>20 experiment on -- on individual people?</p> <p>21 A. So, you would call them</p> <p>22 observational studies.</p> <p>23 Q. Right. Epidemiology</p> <p>24 studies.</p>	<p style="text-align: right;">Page 413</p> <p>1 methods versus experimental ones."</p> <p>2 A. Yeah, I see that.</p> <p>3 Q. Okay. And so what's</p> <p>4 postulated here is an epidemiologist may</p> <p>5 go about this in a different way than if</p> <p>6 you were conducting a clinical trial.</p> <p>7 And the next paragraph describes that</p> <p>8 methodology, correct?</p> <p>9 MR. HEGARTY: Objection to</p> <p>10 form.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Have you ever seen this</p> <p>13 before? I mean, this is your document.</p> <p>14 You are reading it. Have you seen this</p> <p>15 before?</p> <p>16 MR. HEGARTY: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: So I've seen</p> <p>19 it for the first time in probably</p> <p>20 a long time.</p> <p>21 BY MR. TISI:</p> <p>22 Q. Okay.</p> <p>23 A. Okay. So that's why I need</p> <p>24 time to look at it.</p>



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<p>1 Q. No, that's fine. But I just 2 didn't want to -- I didn't want it to be 3 like this was your first time seeing it. 4 This is -- this is your -- this is your 5 work that went in under your name. 6 MR. HUDSON: Objection to 7 form. 8 THE WITNESS: I've already 9 described my role in it. So let 10 me look at the next -- the next 11 paragraph are the Hill criteria. 12 BY MR. TISI: 13 Q. Right. And so the 14 methodology described here is, is what's 15 called the Hill criteria and there are 16 nine, correct? 17 A. Yes. 18 Q. And what it basically says 19 is -- and it says here and it makes an 20 important point. "Hill criteria as 21 they've become known is not simply a 22 checklist or requirements that must be 23 met in order to determine cause and 24 effect relationships."</p>	<p>1 A. That's correct. 2 MR. HEGARTY: Objection to 3 form. 4 BY MR. TISI: 5 Q. All right. And different -- 6 and this is kind of what I talked about 7 at the very beginning of our discussion 8 today, all of these factors here, okay, 9 different epidemiologists can weigh them 10 differently, correct? 11 MR. HUDSON: Objection to 12 form. 13 BY MR. TISI: 14 Q. And it's not unusual that 15 they do, that's science. 16 MR. HUDSON: Objection to 17 form. No question pending. 18 THE WITNESS: So -- 19 BY MR. TISI: 20 Q. Well, let me rephrase the 21 question. 22 A. Yeah, right. 23 Q. Okay. You can do an 24 epidemiology study and see the results.</p>
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<p>1 Do you see that? 2 A. Yes. 3 Q. Okay. So if anybody were to 4 come into court and say, gee, you know, 5 here is the Hill criteria, here are the 6 nine one, and we need to go through and 7 check each one of those, that would be 8 wrong, right? 9 MR. HEGARTY: Objection. 10 MR. SILVER: Objection. 11 BY MR. TISI: 12 Q. And Hill made that point. 13 A. I'm sorry, can you repeat 14 that? 15 Q. Yes. Yes. Hill made -- 16 Hill made the point -- 17 A. So, okay. So I will -- I 18 will say that the Hill criteria are -- 19 are guidelines. They are not really 20 considered criteria. 21 Q. Right. Correct. And so 22 they are not like a checklist or a 23 laundry list or a recipe that has to be 24 met.</p>	<p>1 You do the statistics. You report them. 2 They are what they are, right? 3 A. Yes. 4 Q. Okay. But the decision 5 about making the jump from that 6 Statistical Association to the causal, if 7 there's a causal inference, is one that 8 is one that scientists debate all the 9 time. 10 MR. HUDSON: Objection to 11 form. 12 THE WITNESS: I would say 13 that the -- well, that's the 14 purpose of the IARC proceedings, 15 is to get together experts, review 16 the literature from different 17 aspects of the field. And not -- 18 not just epidemiology. It's 19 animal work, experimental work. 20 And come up with some -- some 21 determination. 22 BY MR. TISI: 23 Q. That's right. And but the 24 process is one of using scientific</p>

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<p style="text-align: right;">Page 418</p> <p>1 judgment, correct?</p> <p>2 A. That's correct.</p> <p>3 Q. There's no magic formula</p> <p>4 here, right?</p> <p>5 MR. HEGARTY: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: It requires</p> <p>8 scientific judgment.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Scientific judgment.</p> <p>11 And oftentimes, scientists</p> <p>12 may weigh these factors differently,</p> <p>13 true?</p> <p>14 MR. HEGARTY: Objection to</p> <p>15 form.</p> <p>16 THE WITNESS: It's possible</p> <p>17 it may happen. But it's possible</p> <p>18 that scientists may be in</p> <p>19 agreement.</p> <p>20 BY MR. TISI:</p> <p>21 Q. And so this is a framework,</p> <p>22 this is not a -- this Hill criteria is a</p> <p>23 framework. And you used -- used the</p> <p>24 word, it is at least a general framework</p>	<p style="text-align: right;">Page 420</p> <p>1 question with most showing odds ratios</p> <p>2 between 1.0 and 2.0," correct?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. And when you say</p> <p>5 that, you mean statistically significant,</p> <p>6 correct?</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: I'm not sure</p> <p>10 that's implicit.</p> <p>11 BY MR. TISI:</p> <p>12 Q. Okay. But it would show a</p> <p>13 point estimate in the range that suggests</p> <p>14 an association?</p> <p>15 MR. HEGARTY: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: With a -- it</p> <p>18 would show -- well, you've seen</p> <p>19 what the meta-analyses are, right?</p> <p>20 BY MR. TISI:</p> <p>21 Q. Right.</p> <p>22 A. And so the -- you know,</p> <p>23 depending on the -- those ranges are</p> <p>24 approximately 1.3, 1.2.</p>
<p style="text-align: right;">Page 419</p> <p>1 for the process.</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 THE WITNESS: So I would --</p> <p>5 I prefer my term, sort of</p> <p>6 guidelines.</p> <p>7 BY MR. TISI:</p> <p>8 Q. Okay. Now the next thing</p> <p>9 that's here I think we can agree to is in</p> <p>10 the overview section. It says -- and you</p> <p>11 start talking about talc.</p> <p>12 And it says, "The</p> <p>13 possibility that perineal talc exposure</p> <p>14 could be associated with the development</p> <p>15 of ovarian cancer was initially derived</p> <p>16 from a case-control study in 1992 (sic)</p> <p>17 Dr. Cramer."</p> <p>18 Do you see that?</p> <p>19 A. Yes.</p> <p>20 MR. HEGARTY: Objection,</p> <p>21 form.</p> <p>22 BY MR. TISI:</p> <p>23 Q. "Since that time a number of</p> <p>24 additional reports have addressed the</p>	<p style="text-align: right;">Page 421</p> <p>1 Q. Okay. And you've</p> <p>2 characterized them as weak effects,</p> <p>3 right? But you say that there is</p> <p>4 actually -- effects of this magnitude are</p> <p>5 often characterized as weak effects.</p> <p>6 Although the definition, exact definition</p> <p>7 of weak effect is debatable, and you go</p> <p>8 on.</p> <p>9 A. Yes, I see that.</p> <p>10 Q. But you make the next point</p> <p>11 on Page 23. Next -- first sentence of</p> <p>12 the next -- next full paragraph. It</p> <p>13 says, "It is important to point out that</p> <p>14 although an association is weak," as you</p> <p>15 call it, "this does not rule out a causal</p> <p>16 connection," correct?</p> <p>17 A. Yes, I see that.</p> <p>18 Q. Okay. In fact, there are</p> <p>19 multiple different kinds of things that</p> <p>20 we accept are causally related that have</p> <p>21 weak statistical associations, correct?</p> <p>22 MR. HEGARTY: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: That I don't</p>



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<p>1 know. And the best way to do that</p> <p>2 would be to actually go through</p> <p>3 all the IARC monographs and look</p> <p>4 at the statistics. That's --</p> <p>5 that's the only way I can make</p> <p>6 that assessment.</p> <p>7 BY MR. TISI:</p> <p>8 Q. IARC is a pretty -- is a</p> <p>9 pretty -- you mentioned IARC a couple of</p> <p>10 times. Is a pretty credible</p> <p>11 organization?</p> <p>12 MR. HEGARTY: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: It's a</p> <p>15 credible organization.</p> <p>16 BY MR. TISI:</p> <p>17 Q. And it's looked at in the</p> <p>18 scientific community with respect?</p> <p>19 MR. HEGARTY: Objection to</p> <p>20 form.</p> <p>21 THE WITNESS: I can't answer</p> <p>22 for everybody.</p> <p>23 BY MR. TISI:</p> <p>24 Q. But you believe that's true?</p>	<p>1 so much.</p> <p>2 But whether you agree or</p> <p>3 disagree with the results that the IARC</p> <p>4 panel came to, the methodology that they</p> <p>5 use is one that's pretty standard in the</p> <p>6 scientific and medical community, true,</p> <p>7 for cause and effect?</p> <p>8 MR. HEGARTY: Objection to</p> <p>9 form.</p> <p>10 THE WITNESS: No. I would</p> <p>11 say it's -- it's unusual.</p> <p>12 BY MR. TISI:</p> <p>13 Q. Why is it unusual?</p> <p>14 A. They -- they have their own</p> <p>15 algorithm. It's kind of difficult to</p> <p>16 describe. But they consider different</p> <p>17 bodies of evidence and then they kind of</p> <p>18 give it sort of certain weights, or</p> <p>19 mechanistic data versus epidemiologic</p> <p>20 data versus animal studies.</p> <p>21 And so there's -- sort of --</p> <p>22 it's rather obscured, there's sort of a</p> <p>23 weighting system. I don't know of other</p> <p>24 groups that use that specific -- the</p>
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<p>1 A. Personally I -- I admire</p> <p>2 IARC and what they do.</p> <p>3 Q. And when you went there for</p> <p>4 talc, they actually looked at the Hill</p> <p>5 criteria, true?</p> <p>6 A. So actually I can't recall</p> <p>7 whether he specifically went through the</p> <p>8 Hill criteria. I think they -- I think</p> <p>9 they probably did. I don't remember</p> <p>10 whether they went through it in terms of</p> <p>11 each one of those items.</p> <p>12 But they probably did in</p> <p>13 terms of their assessment, I'm sure they</p> <p>14 did that, in terms of these are the</p> <p>15 things that are often considered in</p> <p>16 weighing the issues.</p> <p>17 Q. Okay. So --</p> <p>18 A. But I can't say that this is</p> <p>19 the Hill criteria and they went through</p> <p>20 that -- that list.</p> <p>21 Q. Well, even though -- and I</p> <p>22 don't know whether it's true or not. But</p> <p>23 I -- and apparently for the purposes of</p> <p>24 this, I -- it doesn't really matter to me</p>	<p>1 specific ways that IARC does it.</p> <p>2 Q. But it is a methodology that</p> <p>3 is recognized at least in that aspect of</p> <p>4 the medical community, it's not --</p> <p>5 A. It's -- in terms of a --</p> <p>6 doing a comprehensive review of the</p> <p>7 literature, and assessing the literature,</p> <p>8 it's, you know, what they do is</p> <p>9 acceptable.</p> <p>10 Q. Okay. So you make the</p> <p>11 point, it says, "Important to point out</p> <p>12 that although the association is weak,</p> <p>13 this does not rule out a causal</p> <p>14 connection."</p> <p>15 A. I see that.</p> <p>16 Q. Okay. And you agree with</p> <p>17 that?</p> <p>18 A. That's correct.</p> <p>19 Q. Okay. So just because</p> <p>20 something is a 1.3 or a 1.2 or 1.4</p> <p>21 doesn't mean that that does not -- that</p> <p>22 relative risk is not causal, correct?</p> <p>23 You have to look at all the other</p> <p>24 evidence and weigh it?</p>



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<p style="text-align: right;">Page 426</p> <p>1 MR. HEGARTY: Objection to 2 form. 3 THE WITNESS: I'm sorry, can 4 you repeat that? 5 BY MR. TISI: 6 Q. Yeah. Just because a 7 relative risk seen in studies is what you 8 call weak or 1 point -- anything less 9 than a 2.0, that doesn't mean that 10 there's no cause and effect? 11 MR. HEGARTY: Objection to 12 form. 13 THE WITNESS: There are some 14 that would argue that's the case. 15 There's sort of a feeling on 16 some -- anything under a 2.0 is 17 due to bias. That's not something 18 that I ascribe to. 19 BY MR. TISI: 20 Q. Okay. 21 A. So I would certainly 22 consider, you know, weak associations 23 within the realm of all the scientific 24 evidence that goes with it.</p>	<p style="text-align: right;">Page 428</p> <p>1 THE VIDEOGRAPHER: Going off 2 the record. 3:55 p.m. 3 (Short break.) 4 THE VIDEOGRAPHER: We are 5 back on record at 4:15 p.m. 6 BY MR. TISI: 7 Q. Doctor, okay, so I'm in the 8 homestretch now and I'm going to focus on 9 some of the more technical issues related 10 to the studies that you did and relied on 11 in your reports that you sent to the FDA 12 and published in the peer-reviewed 13 medical literature. 14 A. Okay. 15 Q. So going back to our little 16 outline that I gave you in the very 17 beginning, where I am is at Number 4, the 18 reliability and data -- of data and 19 methods in Muscat literature of talcum 20 powder products and ovarian cancer. 21 Okay? 22 A. Yep. 23 Q. So -- 24 (Document marked for</p>
<p style="text-align: right;">Page 427</p> <p>1 Q. So you employ kind of a 2 weight of the evidence methodology, 3 correct? 4 MR. HEGARTY: Objection to 5 form. 6 THE WITNESS: For, for? 7 BY MR. TISI: 8 Q. Cause and effect. You look 9 at the epidemiology studies, you look at 10 the animal studies, you look at the -- 11 you look at the dose-response, you look 12 at biological plausible mechanism. And 13 you basically take that and you apply 14 your best judgment to that and see where 15 the weight of the evidence lies? 16 A. Yes, yes. 17 Q. All right. The next point I 18 want to go to is the last one. 19 MR. HUDSON: You know, 20 Counsel, we've been going almost 21 two hours. Do you think it may be 22 time for an afternoon break? 23 MR. TISI: Yeah. That's 24 fine.</p>	<p style="text-align: right;">Page 429</p> <p>1 identification as Exhibit 2 Muscat-31.) 3 BY MR. TISI: 4 Q. And actually I'm going to 5 mark this as Exhibit Number 31 so we have 6 it for the record. 7 Now, Doctor, when I look at 8 your report that you sent to the FDA and 9 your 2011 article that was published in 10 the European Journal of Cancer 11 Prevention, and indeed all your other 12 articles going back in time, you appear 13 to make four points. And I tried to be 14 fair, and we'll modify this, if I'm not 15 and put them on a slide here so we can 16 talk about each one of them. Okay. 17 You agree that the pooled 18 analysis of epidemiologic studies shows 19 an overall 33 percent increased risk of 20 ovarian cancer, but considerations of the 21 following factors mitigate against a 22 causal inference. 23 First of all, would you 24 agree that that's generally true, that's</p>



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<p style="text-align: right;">Page 430</p> <p>1 what your -- that's what you assumed in 2 your writings based upon Dr. Huncharek's 3 2003 meta-analysis? 4 MR. SILVER: Objection to 5 form. 6 MR. HUDSON: Objection to 7 form. 8 THE WITNESS: So can I 9 qualify that? 10 BY MR. TISI: 11 Q. Sure. And we'll change it 12 on -- on this chart. 13 A. Okay. 14 Q. Any way you can. 15 A. So there have been more 16 recent meta-analyses that I think have 17 incorporated new studies. And so -- 18 Q. In fairness, let me -- let 19 me stop you. 20 A. Okay. 21 Q. Because I'm taking your 22 deposition here as a fact witness and not 23 as a, quote, expert. And I'm really 24 trying to focus on what you wrote in the</p>	<p style="text-align: right;">Page 432</p> <p>1 BY MR. TISI: 2 Q. That's fine. 3 A. But I want to make sure that 4 I know what the data point I'm referring 5 to, that you're referring to in my 6 studies, so I can -- because one point, 7 33 percent, is that from the -- 8 Q. Well, that was -- that was 9 the number that was referred to in your 10 Citizen's Petition in your 2011 study. 11 And I think it was derived from the 12 meta-analysis that Dr. Huncharek did. 13 A. Okay. 14 Q. But whether the number is 15 33 percent or 1.2 or 1.4, in that range. 16 A. In that range. Okay. 17 Q. Okay. So why don't we 18 change it to say -- what numbers can we 19 use? A 20 to 40 percent increase? 20 MR. HEGARTY: Objection to 21 form. 22 THE WITNESS: I'd say I 23 don't have the number off the top 24 of my head.</p>
<p style="text-align: right;">Page 431</p> <p>1 peer-reviewed literature and what you 2 said. Okay. Now, there may have been 3 things after 2011. But you haven't 4 really published in the area since 2007, 5 have you? 6 A. That's correct. 7 Q. Or 2011. 8 So I'm going to kind of keep 9 you to -- and that's a good point. 10 As of 2011, okay, you were 11 of the view that there was a 12 statistically significant increased risk 13 overall when you look at all the studies 14 together in a meta-analysis, but that 15 there were factors that considered -- 16 that mitigated against a causal 17 inference? 18 MR. HEGARTY: Objection to 19 form. 20 MR. HUDSON: Objection to 21 form. 22 THE WITNESS: Okay. So I -- 23 so I don't mean to be 24 obstructionist.</p>	<p style="text-align: right;">Page 433</p> <p>1 BY MR. TISI: 2 Q. Okay. But the number that 3 you used was 33 percent because you 4 referred to the meta-analysis that 5 Dr. Huncharek did, so can we use that 6 number? 7 A. Okay. 8 Q. Knowing that it's a range. 9 MR. HUDSON: Objection to 10 form. 11 THE WITNESS: Okay. 12 BY MR. TISI: 13 Q. But it's a range, it could 14 be 1.2, it could be 1.4. But the number 15 that you had referred to in your reports 16 and publications with Dr. Huncharek was 17 33 percent. 18 MR. HEGARTY: Objection to 19 form. 20 BY MR. TISI: 21 Q. Okay? I mean I can point it 22 out to you if you want. Maybe we'll 23 confirm it when we get to that. Okay? 24 A. Okay.</p>



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<p style="text-align: right;">Page 434</p> <p>1 MR. HEGARTY: Objection to 2 form. 3 BY MR. TISI: 4 Q. But what I really want to 5 get to are the four points here. Number 6 one is, your view was that there was a 7 lack of dose-response relationship, 8 correct? And that's one of the Hill 9 factors, that there was no dose-response 10 relationship between talc and ovarian 11 cancer. 12 A. This is kind of new to me. 13 You are summarizing my conclusions? I 14 just don't know -- 15 Q. Let's go back. Let's go 16 back. Let's go back to Exhibit 17 Number 25. 18 (Brief interruption.) 19 BY MR. TISI: 20 Q. Let's go to Page 24 of your 21 report with Dr. Huncharek in 2009. And 22 this was in response to the Citizen's 23 Petition to add a talc warning. 24 A. Okay.</p>	<p style="text-align: right;">Page 436</p> <p>1 THE WITNESS: I see that. 2 Okay. 3 BY MR. TISI: 4 Q. Okay. But then there was 5 some -- saying, okay, well, let's accept 6 that there is a mild association, and 7 let's talk about whether or not the other 8 Hill factors support a causal inference, 9 correct, and down here it starts with, 10 two paragraphs down, it says, "One of the 11 more persistent findings among 12 epidemiological studies, examining the 13 suspected association, is the lack of 14 dose-response relationship." 15 Do you see that? 16 MR. HEGARTY: Objection to 17 form. 18 THE WITNESS: So I do, but 19 I'd like to make the comment on 20 the previous one. I mean you had 21 pointed out the summary of 22 relative risk which I agreed upon, 23 all right. 24 But it also says that</p>
<p style="text-align: right;">Page 435</p> <p>1 Q. Just for context. 2 A. Okay. 3 Q. On Page 24 it says, first 4 paragraph. 5 A. Yes. 6 Q. It says, "Huncharek et al. 7 initially pooled the data from 15 8 case-control and 1 cohorts analysis 9 yielding a summary risk of 1.33 with a 10 confidence interval of 1.16 to 1.45." 11 Do you see that? 12 A. I see that. 13 Q. That's where the 33 percent 14 increased risk that I put on this slide 15 came from. 16 MR. HEGARTY: Objection to 17 form. 18 THE WITNESS: Okay. 19 BY MR. TISI: 20 Q. But that was in your -- but 21 that was in the report that you signed 22 with Dr. Huncharek? 23 MR. HUDSON: Objection to 24 form.</p>	<p style="text-align: right;">Page 437</p> <p>1 "although this suggests a 2 statistically significant positive 3 association between perineal talc 4 use and ovarian cancer, risk 5 sensitivity analysis demonstrate 6 clear differences in outcome based 7 on study design." 8 BY MR. TISI: 9 Q. Understood. I have this 10 here -- 11 MR. HUDSON: Let him finish 12 his answer, please. 13 THE WITNESS: Yeah -- 14 BY MR. TISI: 15 Q. I have it here on the 16 chart -- 17 MR. HUDSON: Let him finish 18 his answer, please. 19 THE WITNESS: No, but you -- 20 you were summarizing the main 21 points that I was trying to make. 22 Right? And so I -- I agreed that 23 the 1.33 by -- 24 (Document marked for</p>

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<p style="text-align: right;">Page 438</p> <p>1 identification as Exhibit 2 Muscat-32.) 3 BY MR. TISI: 4 Q. Understood. And it says 5 here lack of consistency between study 6 designs on the chart. 7 A. Okay. 8 Q. Look at the -- look at the 9 chart. And I listed at least four -- 10 four arguments that made against a causal 11 inference. One is a lack of 12 dose-response relationship. 13 A. Okay. 14 Q. That's here. Number 2 is 15 lack -- I took them a little bit out of 16 order because I want to discuss them in 17 the order. 18 A. Okay. 19 Q. Lack of a biologically 20 plausible mechanism. Do you see that, 21 and that's an argument you've made? 22 A. Okay. 23 Q. Right? And the lack of 24 consistency between study -- different</p>	<p style="text-align: right;">Page 440</p> <p>1 that. 2 Q. Then that's fine. Let's -- 3 let's deal with this right now. 4 A. Okay. But if you want to 5 talk about more general -- yeah. 6 Q. Let's talk about more 7 general, because I don't want to -- I 8 don't want to dance around the maypole 9 with you about when -- what you said and 10 when. 11 I'm going to represent to 12 you that I've read all your literature. 13 And these four points are points that 14 you've made consistently. 15 Number one, that there does 16 not appear to be a dose-response 17 relationship and, in fact, there appears 18 to be an inverse dose-response 19 relationship in some studies. Does that 20 sound familiar to you? 21 MR. HEGARTY: Objection to 22 form. 23 THE WITNESS: Yes. 24 BY MR. TISI:</p>
<p style="text-align: right;">Page 439</p> <p>1 study designs which is the point you just 2 made, correct? 3 A. Okay, yes. 4 Q. Right? And uncontrolled 5 confounding. 6 A. Yes. 7 Q. All right. And those are 8 points that you made, not only in this 9 paper, but in the published literature 10 and in your meta-analyses and your 11 appearance before NTP and the FDA. 12 This -- these four things have been 13 consistent points of view that you have 14 raised? 15 MR. HEGARTY: Objection to 16 form. 17 THE WITNESS: So I -- just 18 to be clear, I did not appear 19 before the NTP had submitted 20 something. 21 BY MR. TISI: 22 Q. Fine. 23 A. But -- and honestly for me 24 to -- I'd have to go back and look at all</p>	<p style="text-align: right;">Page 441</p> <p>1 Q. Okay. You also made the 2 point that there is -- that there is, in 3 your view, a lack of biologically 4 plausible mechanism which would explain a 5 risk for -- which would raise the 6 inference of causation. 7 MR. HEGARTY: Objection. 8 THE WITNESS: Yeah, I have 9 talked about biological 10 plausibility. I can't recall 11 specifically as it relates to the 12 inference. But I mean it sounds 13 familiar, but I'd really have to 14 look at the context. 15 BY MR. TISI: 16 Q. Okay. We're going to talk 17 about it because it's in your paper here. 18 A. Okay. 19 Q. Okay. The next thing you 20 talk about is the lack of consistency 21 between different study designs. 22 A. Okay. 23 Q. Right? That's a point you 24 just mentioned.</p>



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<p style="text-align: right;">Page 442</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And that there might</p> <p>3 be uncontrolled founding -- confounding,</p> <p>4 and one of the issues you raised is</p> <p>5 smoking.</p> <p>6 A. Okay.</p> <p>7 Q. Does that sound familiar to</p> <p>8 you?</p> <p>9 A. No.</p> <p>10 MR. HEGARTY: Objection to</p> <p>11 form.</p> <p>12 BY MR. TISI:</p> <p>13 Q. It doesn't?</p> <p>14 A. That I've said uncontrolled</p> <p>15 confounding is smoking?</p> <p>16 Q. That -- that the studies</p> <p>17 that looked at talc and ovarian cancer</p> <p>18 did not control for smoking.</p> <p>19 A. I -- I can't recall.</p> <p>20 Q. Okay. We'll talk about</p> <p>21 that.</p> <p>22 A. Okay.</p> <p>23 Q. So I'm going to kind of take</p> <p>24 these in order in which I listed them and</p>	<p style="text-align: right;">Page 444</p> <p>1 table?</p> <p>2 A. I saw a table.</p> <p>3 Q. Okay. So you're referring</p> <p>4 the FDA specifically to a specific table</p> <p>5 in Dr. -- Dr. Huncharek's 2003</p> <p>6 meta-analysis?</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: I'm sorry, can</p> <p>10 I just look at this for a second?</p> <p>11 BY MR. TISI:</p> <p>12 Q. Sure.</p> <p>13 A. This would be helpful if I</p> <p>14 could actually see -- if we are going to</p> <p>15 talk about this, if I can see Table 2.</p> <p>16 Q. Absolutely. You're going</p> <p>17 to -- you're going to be spending a lot</p> <p>18 of time with Table 2.</p> <p>19 A. Okay.</p> <p>20 Q. Okay. But it refers the FDA</p> <p>21 to Table 2 in the meta-analysis, correct?</p> <p>22 A. That's correct.</p> <p>23 Q. Okay. And I'm going to mark</p> <p>24 Table 2.</p>
<p style="text-align: right;">Page 443</p> <p>1 talk about them.</p> <p>2 A. Okay.</p> <p>3 Q. Okay. All right. So let's</p> <p>4 talk about lack of dose-response</p> <p>5 relationship first.</p> <p>6 On Page 24 of your Citizen's</p> <p>7 Petition that you sent to the FDA, you</p> <p>8 say, one of the -- on the last -- right</p> <p>9 there.</p> <p>10 "One of the more persistent</p> <p>11 findings among epidemiological studies,</p> <p>12 examining the suspected association, is</p> <p>13 the lack of dose-response relationship."</p> <p>14 Do you see that?</p> <p>15 A. I see that.</p> <p>16 Q. And it says, "Table 2 of</p> <p>17 Huncharek et al. meta-analysis displays a</p> <p>18 dose-response data for those including</p> <p>19 studies providing such information."</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. And we looked at Table 2</p> <p>23 before. Do you remember early on in the</p> <p>24 deposition I showed you a dose-response</p>	<p style="text-align: right;">Page 445</p> <p>1 I'll get it another day.</p> <p>2 Let's -- let's bring it up</p> <p>3 on the screen if you don't mind.</p> <p>4 I'll tell you what. Go to</p> <p>5 your binder that I put in front of you.</p> <p>6 Tab 4 is the meta-analysis, and there is</p> <p>7 Table 2. Do you see it?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And you actually --</p> <p>10 as I talked to you about before, you</p> <p>11 actually reproduced that table. Now that</p> <p>12 table --</p> <p>13 MR. TISI: Can you bring it</p> <p>14 up, please?</p> <p>15 BY MR. TISI:</p> <p>16 Q. All right. Let's just keep</p> <p>17 going.</p> <p>18 You actually reproduced that</p> <p>19 table in your 2011 published study,</p> <p>20 correct?</p> <p>21 MR. HUDSON: Objection to</p> <p>22 form.</p> <p>23 MR. HEGARTY: Objection to</p> <p>24 form.</p>

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<p style="text-align: right;">Page 446</p> <p>1 BY MR. TISI: 2 Q. Go to -- go to Exhibit 3 Number 24. And here it's Table 3. And 4 it says on the first column, it says, 5 "Table 3 derived from data presented in 6 the meta-analysis by Huncharek, et al. 7 displays dose-response data for those 8 included studies providing such 9 information." 10 Do you see that? 11 A. I'm sorry, where am I 12 supposed to be reading from? 13 Q. Okay. Look at the first -- 14 look at the first column on your 2011 15 study -- published article. It says -- 16 go down. 17 Go down. It says here, "One 18 of the more persistent findings among 19 epidemiologic studies examining this 20 relationship is the lack of dose-response 21 relationship." 22 In fact, that's the exact 23 sentence that we read from the Citizen's 24 Petition report, right?</p>	<p style="text-align: right;">Page 448</p> <p>1 A. Okay. 2 Q. So I'm going to show you and 3 this may make your life easier because 4 it's easy to read. 5 MR. TISI: What's the next 6 exhibit, please. 7 (Document marked for 8 identification as Exhibit 9 Muscat-33.) 10 BY MR. TISI: 11 Q. Can I have Number 33. I 12 actually blew up, and maybe this will 13 help us here. Table -- this is actually 14 Huncharek 2011. 15 I'm going to give you this 16 copy. I just changed it because it 17 should be 2011. This is Table 3 from 18 your study so it's easier to read. 19 A. Okay. 20 Q. Okay? So you can put the 21 study down and we can actually work with 22 it. 23 Now, just for recollection, 24 this is your study from 2011 that</p>
<p style="text-align: right;">Page 447</p> <p>1 A. Okay. Okay. 2 Q. Right? "Table 3 derived 3 from the data presented by the 4 meta-analysis of Huncharek et al. 5 displays dose-response data from those 6 included studies providing such 7 information." 8 Do you see that? 9 A. I see that. 10 Q. Okay. And if you look at 11 Table 3, it is exactly Table 2 from 12 your -- the meta-analysis with one 13 exception. You actually are kind enough 14 to list the actual studies along the Y 15 axis. 16 MR. HEGARTY: Objection. 17 BY MR. TISI: 18 Q. Instead of referring by 19 numbers. 20 I will tell you that I 21 checked all the numbers. They all look 22 the same. 23 A. Okay, okay. 24 Q. Okay?</p>	<p style="text-align: right;">Page 449</p> <p>1 incorporates this chart that was derived 2 from the 2003 meta-analysis that was also 3 sent to the FDA. 4 A. Okay. 5 Q. All right. Do you follow 6 me? 7 A. Yes. 8 Q. All right. Now, do you have 9 a copy of the 2003 article? 10 A. Yes. 11 Q. Would you please -- have you 12 ever carefully looked at this article, 13 sir? 14 A. The 2003 meta-analysis? 15 Q. Mm-hmm. 16 A. Yeah, I've seen it. 17 Q. Have you read it carefully 18 before citing it to the FDA and 19 republishing it in 2011? 20 MR. HEGARTY: Objection to 21 form. 22 THE WITNESS: I've looked at 23 it. 24 BY MR. TISI:</p>

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<p>1 Q. Did you carefully look at it 2 to make sure it was accurate and 3 complete? 4 A. So I was not an author on 5 it. So I didn't go through word by word. 6 I have looked at this. 7 Q. It's a pretty sloppy 8 article, isn't it? 9 MR. HUDSON: Objection to 10 form. 11 BY MR. TISI: 12 Q. In fact, it's a really 13 sloppy article, isn't it? 14 MR. HUDSON: Objection to 15 form. 16 THE WITNESS: I wouldn't 17 make that comment. 18 BY MR. TISI: 19 Q. Well, let's -- let's see if 20 we can go through it. On Page 1958 of 21 Dr. Huncharek's 2003 article. 22 A. Mm-hmm. 23 Q. On the left-hand column, 24 referring to Table 2, the dose-response</p>	<p>1 THE WITNESS: I see that. 2 BY MR. TISI: 3 Q. Okay. That's wrong, 4 correct? 5 MR. HEGARTY: Objection to 6 form. 7 THE WITNESS: I can't say 8 for certain. 9 BY MR. TISI: 10 Q. It appears to be wrong, 11 correct? 12 A. No, I can't say for certain. 13 Q. He says seven studies were 14 included in the analysis and he displays 15 nine. 16 A. Okay. So without having to 17 go back and -- and compare them, 18 sometimes it's the same study and there 19 are updates. So that may be the case. 20 Like for instance, Cramer, 21 Dr. Cramer had published multiple -- 22 multiple publications so -- 23 Q. Sometimes -- 24 A. Can I finish, please?</p>
Page 451	Page 453
<p>1 data that we are talking about here. 2 MR. TISI: Could you please 3 bring that up. 4 BY MR. TISI: 5 Q. If you go to the first 6 paragraph, second full paragraph on the 7 left-hand side. It says, "Seven studies 8 included" -- he's talking about the 9 studies, right? 10 A. Okay. 11 Q. "Seven studies included 12 dose-response data stratified by the 13 number of talc applications to the 14 perineum per month Table 2." 15 Do you see that. 16 A. Mm-hmm. 17 Q. Could you do me a favor and 18 count the number of studies that are 19 included in Table 2? 20 A. Nine. 21 Q. He says there are seven, 22 correct? 23 MR. HEGARTY: Objection to 24 form.</p>	<p>1 Q. Sure. 2 A. Okay. So that may be the 3 same study, the New England case-control 4 study. And there may be multiple 5 references. I'll -- 6 Q. But let's just -- 7 MR. HUDSON: Let him finish 8 his answer. 9 BY MR. TISI: 10 Q. Let's talk about it. 11 MR. HUDSON: Just a minute. 12 Let him finish his answer, please. 13 BY MR. TISI: 14 Q. Go ahead, please. 15 A. Yeah, thank you. 16 So I can't automatically 17 make the assumption that this is 18 incorrect. 19 I -- I know for a fact in 20 meta-analyses, one of the challenges that 21 is faced is that there are sometimes 22 multiple reports from the same study. 23 Q. Right. Well -- 24 A. So --</p>

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<p style="text-align: right;">Page 454</p> <p>1 Q. -- it looks like Dr. -- 2 Dr. -- 3 A. Huncharek. 4 Q. -- Huncharek tried to take 5 care of that. Let's go back to page -- 6 the page before where he talks about 7 results. 8 A. Okay. 9 Q. Okay. He talks about the -- 10 he talks about the literature search. 11 See the results section? "The literature 12 search revealed 17 studies that appeared 13 to meet the protocol specification and 14 full papers were obtained for review. 15 Further review showed the paper by 16 Hankinson used the same data as the 17 subsequent paper by Gertig from the same 18 laboratory. Therefore, only 12 19 references were included in the 20 meta-analysis. The remaining 16 papers 21 met protocol specified include criteria." 22 So it looks like he went 23 through the process of sorting the 24 studies, didn't he?</p>	<p style="text-align: right;">Page 456</p> <p>1 Hankinson was included." Do you see 2 that? 3 A. Yeah, I see that. 4 Q. Okay. So if you look at -- 5 but if you look at the next page, and it 6 says, "Overview of included studies." 7 One, two, three, four, five, six, seven, 8 eight -- eight down, he included Gertig 9 but not Hankinson. 10 A. Yeah, I think that's 11 correct. 12 Q. Yeah, it is. And how about 13 this -- 14 A. Yeah, I think what he did 15 was correct. I don't know -- 16 Q. He said he took out 17 Hankinson -- he said he took out Gertig 18 because Hankinson was repetitive, but he 19 kept Gertig in and he took Hankinson out. 20 He says, "Further review 21 showed the paper by Hankinson, reference 22 12, used the same data as the subsequent 23 paper by Gertig. Therefore, only 24 Hankinson was included, reference 12."</p>
<p style="text-align: right;">Page 455</p> <p>1 MR. HEGARTY: Where were you 2 just reading from, counsel? 3 MR. TISI: Page -- 4 MR. HEGARTY: 1957? 5 MR. TISI: 1956 under the 6 results section. 7 BY MR. TISI: 8 Q. He went through the sorting 9 process. 10 A. Okay. 11 Q. All right. Of course this 12 is a mistake too, right? 13 MR. HUDSON: Objection to 14 form. 15 BY MR. TISI: 16 Q. He looked at -- well, look 17 at -- it says -- here it says that the 18 paper by Hankinson used the same data as 19 the subsequent paper by Gertig. And he 20 says -- do you see that? 21 MR. HEGARTY: Objection to 22 form. 23 BY MR. TISI: 24 Q. It says, "Therefore, only</p>	<p style="text-align: right;">Page 457</p> <p>1 Right? 2 A. I see that, yes. 3 Q. And if you look at the next 4 page, he didn't include Hankinson, he 5 included Gertig. 6 A. Okay. 7 Q. So it was an error. 8 MR. HEGARTY: Objection to 9 form. 10 THE WITNESS: There might be 11 an error in that. 12 BY MR. TISI: 13 Q. Okay. And there's errors 14 throughout this paper. Let me give you 15 another example, sir. 16 If you go to Page 86 -- I 17 mean there are just spelling errors even. 18 MR. HEGARTY: Objection to 19 form. 20 BY MR. TISI: 21 Q. Look at -- look at Page 22 1958. Very top sentence. "Given the 23 lack of statistical heterogeneity." 24 That's even spelled wrong, isn't it?</p>

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<p style="text-align: right;">Page 458</p> <p>1 A. I'm sorry, where are we?</p> <p>2 Q. First -- first full sentence</p> <p>3 on the first paragraph --</p> <p>4 A. Oh, I see. Yeah, there's a</p> <p>5 typo there.</p> <p>6 Q. Even spelling errors?</p> <p>7 A. Yes.</p> <p>8 Q. This wasn't peer reviewed</p> <p>9 very carefully, was it?</p> <p>10 MR. HUDSON: Objection to</p> <p>11 form.</p> <p>12 THE WITNESS: It was peer</p> <p>13 reviewed.</p> <p>14 BY MR. TISI:</p> <p>15 Q. Okay. So let's talk about</p> <p>16 the data. Now going back to it, it says</p> <p>17 there were seven studies that met the</p> <p>18 criteria but there are nine listed in</p> <p>19 Table 2, right?</p> <p>20 A. That's correct.</p> <p>21 Q. All right. Now, let's go to</p> <p>22 Table 3 that's actually reproduced in</p> <p>23 your -- this -- again, for the record,</p> <p>24 Table 2 was reproduced in your 2011</p>	<p style="text-align: right;">Page 460</p> <p>1 MR. HUDSON: 33.</p> <p>2 MR. TISI: 33.</p> <p>3 (Document marked for</p> <p>4 identification as Exhibit</p> <p>5 Muscat-34.)</p> <p>6 BY MR. TISI:</p> <p>7 Q. This is Exhibit Number 34,</p> <p>8 sir.</p> <p>9 And this for the record</p> <p>10 is --</p> <p>11 MR. TISI: Actually can I</p> <p>12 have one copy? I'll give it back</p> <p>13 to you, but...</p> <p>14 BY MR. TISI:</p> <p>15 Q. It has in front of it</p> <p>16 Table 2 from Huncharek 2003. Table 3,</p> <p>17 and actually it should say -- it should</p> <p>18 be -- why don't you write 2011 on top.</p> <p>19 Do you see that?</p> <p>20 A. Okay.</p> <p>21 Q. And then behind it are the</p> <p>22 studies that are referred to.</p> <p>23 A. Okay.</p> <p>24 Q. Okay. So that we can refer</p>
<p style="text-align: right;">Page 459</p> <p>1 article as Table 3, exhibit -- what is</p> <p>2 that -- what is that exhibit number? 24.</p> <p>3 A. Okay. Mm-hmm.</p> <p>4 Q. Yes, correct.</p> <p>5 A. Yes.</p> <p>6 Q. All right. All right. So</p> <p>7 let me give you -- I created and I hope</p> <p>8 this will help us here. I'm going to</p> <p>9 hand you Exhibit Number 25.</p> <p>10 This is a binder with --</p> <p>11 MR. HUDSON: Is this a new</p> <p>12 25?</p> <p>13 MR. TISI: Is it -- is</p> <p>14 this -- I thought 24 was the last</p> <p>15 one.</p> <p>16 I'm sorry. I miss -- I</p> <p>17 miss -- what number are we on?</p> <p>18 What number are we?</p> <p>19 MR. HUDSON: I think we are</p> <p>20 on 34. But I think we need to get</p> <p>21 confirmation.</p> <p>22 MR. TISI: Okay. 34. I</p> <p>23 wanted to make -- what did I make</p> <p>24 that chart over there?</p>	<p style="text-align: right;">Page 461</p> <p>1 to them.</p> <p>2 A. Okay.</p> <p>3 Q. All right. So this way you</p> <p>4 can make your life a little bit easier.</p> <p>5 All right. So let's go through this.</p> <p>6 First, let's -- let's</p> <p>7 actually -- let me actually go through</p> <p>8 this. First study is a study by Booth</p> <p>9 1989.</p> <p>10 First of all, you agree with</p> <p>11 me as an epidemiologist, numbers matter,</p> <p>12 right? You don't want to make errors</p> <p>13 with numbers?</p> <p>14 A. You always try and be</p> <p>15 correct.</p> <p>16 Q. Right. You don't try to be</p> <p>17 correct, you have to be correct?</p> <p>18 A. Yes.</p> <p>19 Q. Okay. You can't express</p> <p>20 wrong confidence intervals. You can't</p> <p>21 round numbers up or down. You can't --</p> <p>22 you can't say you are doing one thing and</p> <p>23 do another. You've got to be accurate,</p> <p>24 right?</p>

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<p style="text-align: right;">Page 462</p> <p>1 A. Yes.</p> <p>2 Q. All right. Now, what Dr. --</p> <p>3 let's talk about the Booth study. 1989.</p> <p>4 Turn to Booth 575.</p> <p>5 A. I'm sorry.</p> <p>6 Q. I'm sorry, I made a -- I did</p> <p>7 it wrong. I'm sorry, Page 596.</p> <p>8 Now, first of all, let's</p> <p>9 explain for the judge and the jury what</p> <p>10 this is. What doctor -- if you go back</p> <p>11 to the original article, Dr. Huncharek</p> <p>12 says, he says, the data showed a</p> <p>13 comparison was made across these studies,</p> <p>14 the nine studies which he said were</p> <p>15 seven, but it's nine.</p> <p>16 Comparing the lowest</p> <p>17 recorded exposure category with the</p> <p>18 highest exposure level. Do you see that?</p> <p>19 A. I'm sorry, which -- which</p> <p>20 page is that?</p> <p>21 Q. Okay.</p> <p>22 A. Sorry.</p> <p>23 Q. It's page --</p> <p>24 A. I'm sorry. Of the Huncharek</p>	<p style="text-align: right;">Page 464</p> <p>1 on the bottom.</p> <p>2 For each study?</p> <p>3 A. No, it looks like the --</p> <p>4 Q. Let me -- let me see if I</p> <p>5 can explain it.</p> <p>6 A. It looks like the --</p> <p>7 Q. For each study --</p> <p>8 A. Yes.</p> <p>9 Q. -- if it's expressed in</p> <p>10 the -- in years of talc use, it's in the</p> <p>11 first column, right?</p> <p>12 A. That's correct.</p> <p>13 Q. If it's expressed in</p> <p>14 frequency applications, it's in the --</p> <p>15 it's in the second column.</p> <p>16 A. That's correct.</p> <p>17 Q. All right. And he</p> <p>18 explains -- he provides all the data,</p> <p>19 right, with the lowest exposure category</p> <p>20 on top, to the highest. So for example,</p> <p>21 one application per month, four</p> <p>22 applications per month, 30 -- 30</p> <p>23 applications per month, everyday.</p> <p>24 A. I'm sorry, I just need a</p>
<p style="text-align: right;">Page 463</p> <p>1 meta-analysis?</p> <p>2 Q. Yes.</p> <p>3 A. Okay. I'm sorry. Can you</p> <p>4 point out --</p> <p>5 Q. Yes. The second full</p> <p>6 paragraph. It says, "Seven studies</p> <p>7 included dose-response data stratified by</p> <p>8 talc applications to the perineum per</p> <p>9 month."</p> <p>10 Of course we know that there</p> <p>11 are nine listed in Table 2, right?</p> <p>12 A. That's correct.</p> <p>13 Q. "A comparison was made</p> <p>14 across these studies comparing the lowest</p> <p>15 recorded exposure category with the</p> <p>16 highest exposure level."</p> <p>17 Right?</p> <p>18 A. I see that.</p> <p>19 Q. All right. And if you look</p> <p>20 at the chart, your chart on Number 33,</p> <p>21 Exhibit Number 33, the first column,</p> <p>22 it -- both of these display the highest</p> <p>23 exposure category and the lowest exposure</p> <p>24 category. The highest on top, the lowest</p>	<p style="text-align: right;">Page 465</p> <p>1 little time to look at this. Okay.</p> <p>2 Q. Did you find it? All right.</p> <p>3 So now let's go to the chart</p> <p>4 in Booth where that data is taken from.</p> <p>5 And I believe it's Table 11 on Page 596.</p> <p>6 Do you see that?</p> <p>7 A. 12.</p> <p>8 Q. On page -- Table 12,</p> <p>9 correct.</p> <p>10 A. Okay.</p> <p>11 Q. You see -- you follow me?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. Now, there are four</p> <p>14 exposure categories: Rarely, monthly,</p> <p>15 weekly and daily, correct?</p> <p>16 MR. HUDSON: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: So technically</p> <p>19 five including never.</p> <p>20 BY MR. TISI:</p> <p>21 Q. Right. But let's --</p> <p>22 A. Right.</p> <p>23 Q. Never has no exposure so</p> <p>24 it's not really an exposure category. If</p>

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<p style="text-align: right;">Page 466</p> <p>1 you're going to include --</p> <p>2 A. It is a reference category.</p> <p>3 Q. It is a reference category.</p> <p>4 A. Right.</p> <p>5 Q. Okay. But the -- but the</p> <p>6 lowest exposure category is actually</p> <p>7 rarely?</p> <p>8 A. Yes.</p> <p>9 Q. Right? And Dr. --</p> <p>10 Dr. Huncharek says he included the lowest</p> <p>11 category in his chart. But he doesn't</p> <p>12 include that category, does he?</p> <p>13 He actually includes</p> <p>14 monthly, because you see the relative</p> <p>15 risk of .07, correct?</p> <p>16 A. Yes, I see that.</p> <p>17 Q. Okay. So that's -- he's</p> <p>18 reporting something different than he</p> <p>19 said he was going to do, correct? He</p> <p>20 said he was going to report the lowest</p> <p>21 exposure category, but rarely -- he does</p> <p>22 not report the lowest exposure category</p> <p>23 in Booth, does he?</p> <p>24 MR. HUDSON: Objection to</p>	<p style="text-align: right;">Page 468</p> <p>1 Q. The only -- the only place</p> <p>2 he says, he says, "The comparison made</p> <p>3 across these studies comparing lowest</p> <p>4 reported exposure category with the</p> <p>5 highest exposure level." That's what he</p> <p>6 said he did.</p> <p>7 MR. HUDSON: Objection to</p> <p>8 form. No question is pending.</p> <p>9 BY MR. TISI:</p> <p>10 Q. And he doesn't appear to</p> <p>11 have done that, correct?</p> <p>12 MR. HEGARTY: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: Oh, I -- I</p> <p>15 think I understand what he did.</p> <p>16 BY MR. TISI:</p> <p>17 Q. Well, I'm asking you, did he</p> <p>18 do what he said he did? Did he use the</p> <p>19 lowest exposure category?</p> <p>20 A. This is why I needed to have</p> <p>21 a look. I think for the purposes of</p> <p>22 meta-analysis, he probably did, and --</p> <p>23 and the reason I say that is because if</p> <p>24 there are -- like for instance, it's the</p>
<p style="text-align: right;">Page 467</p> <p>1 form.</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 THE WITNESS: I have to go</p> <p>5 look at it carefully. I mean it</p> <p>6 could be correct, but it depends</p> <p>7 on how he defined his methods.</p> <p>8 BY MR. TISI:</p> <p>9 Q. Okay.</p> <p>10 A. It's like...</p> <p>11 Q. Well, his methods don't</p> <p>12 explain it. I will offer -- I will tell</p> <p>13 you that his methods are very sparse.</p> <p>14 A. Okay.</p> <p>15 Q. We'll ask Dr. Huncharek,</p> <p>16 but -- you can take a look at it if you</p> <p>17 want.</p> <p>18 A. Okay.</p> <p>19 Q. But I'm telling you, it's</p> <p>20 not there.</p> <p>21 A. Okay.</p> <p>22 MR. HUDSON: Objection to</p> <p>23 form.</p> <p>24 BY MR. TISI:</p>	<p style="text-align: right;">Page 469</p> <p>1 low -- if the lowest exposure category of</p> <p>2 which is common across a different study.</p> <p>3 So for example, if rarely is</p> <p>4 not in the other studies, then that</p> <p>5 wouldn't be included in the</p> <p>6 meta-analysis.</p> <p>7 Q. Well, how do you know that?</p> <p>8 He didn't describe his methods.</p> <p>9 A. He -- well, I'd have to go</p> <p>10 back and look at this. But I'm just --</p> <p>11 I'm explaining as to you as to how this</p> <p>12 can occur. Okay.</p> <p>13 So in a meta-analysis, maybe</p> <p>14 he was not very specific with it. But,</p> <p>15 the lowest exposure category would be the</p> <p>16 lowest exposure category of all the</p> <p>17 studies.</p> <p>18 So if there -- these other</p> <p>19 studies for example, did not report</p> <p>20 rarely, they wouldn't appear in the</p> <p>21 meta-analysis.</p> <p>22 Q. But he didn't say that,</p> <p>23 that's not what he said. People should</p> <p>24 be able to replicate and not assume,</p>

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<p style="text-align: right;">Page 470</p> <p>1 right?</p> <p>2 MR. HEGARTY: Objection to</p> <p>3 form.</p> <p>4 MR. HUDSON: Objection to</p> <p>5 form.</p> <p>6 BY MR. TISI:</p> <p>7 Q. We talked about that before.</p> <p>8 He -- his paper says, "A comparison was</p> <p>9 made across these studies comparing the</p> <p>10 lowest recorded exposure category with</p> <p>11 the highest exposure category."</p> <p>12 Correct? That's what he</p> <p>13 said he did.</p> <p>14 MR. HEGARTY: Objection to</p> <p>15 form.</p> <p>16 THE WITNESS: So -- I'm</p> <p>17 sorry, let me go back and read</p> <p>18 that, okay?</p> <p>19 So I can't find it right</p> <p>20 now.</p> <p>21 That's what he said. And</p> <p>22 perhaps the wording wasn't</p> <p>23 correct. But it is -- he did it</p> <p>24 correctly though.</p>	<p style="text-align: right;">Page 472</p> <p>1 Q. There was more mistakes in</p> <p>2 this chart.</p> <p>3 A. There was --</p> <p>4 Q. Let's go to the next one.</p> <p>5 The Cook -- the Chang paper which should</p> <p>6 be the next one in your list. That's the</p> <p>7 second reference, right?</p> <p>8 A. Yes.</p> <p>9 Q. Let's go back. That would</p> <p>10 be Chang. We talked about Booth. Let's</p> <p>11 talk about Chang.</p> <p>12 A. Okay.</p> <p>13 Q. The exposure categories are</p> <p>14 contained in Table 2 on Page 399, are</p> <p>15 they not?</p> <p>16 A. Yes.</p> <p>17 Q. And if we look at Table 2,</p> <p>18 the less than 30, do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. What is the relative risk?</p> <p>21 A. 1.697.</p> <p>22 Q. What is -- what is what</p> <p>23 Dr. Chang -- Dr. -- Dr. Huncharek rounded</p> <p>24 that number up, didn't he, to 1.7? It's</p>
<p style="text-align: right;">Page 471</p> <p>1 BY MR. TISI:</p> <p>2 Q. Okay.</p> <p>3 A. He did it correctly in a way</p> <p>4 that is reproducible, because -- and I</p> <p>5 can't speak for him, because I have to go</p> <p>6 through each one of these studies that he</p> <p>7 cited.</p> <p>8 Q. Okay.</p> <p>9 A. But my sense, as I</p> <p>10 understand this, as I read this, and as</p> <p>11 you point this out, and how I know that</p> <p>12 meta-analysis is done, is that those --</p> <p>13 that that particular category was</p> <p>14 probably not in the other studies that</p> <p>15 would have required some further</p> <p>16 explanation. Perhaps he should have done</p> <p>17 that to be absolutely clear.</p> <p>18 But I think this was done</p> <p>19 correctly.</p> <p>20 Q. That wasn't his only</p> <p>21 mistake, was it?</p> <p>22 MR. HUDSON: Objection to</p> <p>23 form.</p> <p>24 BY MR. TISI:</p>	<p style="text-align: right;">Page 473</p> <p>1 not what Dr. Chang reported, was it?</p> <p>2 A. So that's correct. He</p> <p>3 rounded up from 1.697 to 1.7.</p> <p>4 Q. Why didn't he use the number</p> <p>5 that Dr. Chang reported?</p> <p>6 MR. HUDSON: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: It depends on</p> <p>9 the journal. Sometimes journals</p> <p>10 only want you to report to one</p> <p>11 significant digit. Okay.</p> <p>12 That's -- I mean there's no --</p> <p>13 there's no difference between</p> <p>14 1.697 and 1.7. It really depends</p> <p>15 on the journal. It's not exactly</p> <p>16 the same, we can see that. But I</p> <p>17 don't see anything wrong with it.</p> <p>18 BY MR. TISI:</p> <p>19 Q. Well, he also changed the</p> <p>20 confidence interval, didn't he?</p> <p>21 Confidence interval is</p> <p>22 different. The Chang study has a</p> <p>23 confidence interval from 1.08 to 2.60 and</p> <p>24 he has 1.08 to 2.59.</p>



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<p>1 A. Yeah, I see that.  2 Q. It's different, right?  3 A. Yeah, it's different.  4 Q. All right.  5 A. But there's not a problem  6 with it.  7 Q. Okay.  8 A. Can I --  9 Q. Where did he pull that  10 number from?  11 A. Can I explain it?  12 MR. HUDSON: Objection to  13 form.  14 THE WITNESS: You asked --  15 you asked me if it was different  16 and I said -- but now I'm going to  17 explain to you how it's different.  18 BY MR. TISI:  19 Q. Okay. Tell me how it's  20 different.  21 A. Okay. So this is -- in the  22 Chang analysis, this is an adjusted  23 confidence interval.  24 The Huncharek analysis is an</p>	<p>1 one. Let's go to Cook.  2 Now, with Cook, the exposure  3 category is on Table 3, correct?  4 A. That's correct.  5 Q. And you have to do a little  6 math here, but he converted days to  7 months, correct, or to years? They use  8 lifetime -- lifetime days and he just  9 converted them to years.  10 A. Okay.  11 MR. HEGARTY: Objection to  12 form.  13 THE WITNESS: Yeah, I don't  14 know how the conversion was done.  15 BY MR. TISI:  16 Q. Okay. Well, he uses  17 overlapping categories, right? So his  18 categories, if you look at the categories  19 in the Cook paper, it goes less than  20 2,000, then it goes 2,001 to 5,000 and  21 5,001 to 10,000. Do you see that,  22 there's no overlapping categories?  23 A. Yes, I see that.  24 Q. Do you see how Dr. Huncharek</p>
Page 475	Page 477
<p>1 unadjusted confidence interval. That  2 means that he would go back and  3 recalculate the confidence interval as an  4 adjusted confidence interval.  5 Q. Well, he actually goes ahead  6 and totally changes the greater than 40  7 category, doesn't he? He has a greater  8 than 40 -- I'm sorry, greater than 40  9 category as a .96, correct?  10 A. Yes.  11 Q. Okay. And here what do they  12 say?  13 A. Sorry, this is so small I'm  14 having a hard time reading it. 0.865.  15 Q. Okay. It's a different  16 number, is it not?  17 A. It is different. And it's  18 correct. That's the way you do the  19 meta-analysis.  20 Q. So he changed the numbers?  21 A. He didn't change the  22 numbers. He calculated his own numbers  23 based on the data.  24 Q. Okay. Let's go to the next</p>	<p>1 uses overlapping categories? He goes  2 from 5 -- zero to 5.5, 5.5 to 13.5, 13.5  3 to 27. Do you see that?  4 A. So I don't know if they are  5 overlapping. There is a -- I mean the  6 age -- the range is defined with the same  7 number, that's correct.  8 Q. Well, the third category is  9 also incorrect as well. It says a 1.2  10 relative risk with a confidence interval  11 of .5 to 2.4?  12 MR. HEGARTY: Objection to  13 form.  14 THE WITNESS: I'm sorry, can  15 you repeat what you're comparing,  16 which to which?  17 BY MR. TISI:  18 Q. Yeah. It says a confidence  19 interval -- a relative risk of 1.2. Do  20 you see that?  21 A. In the Cook paper?  22 Q. Yes.  23 A. 1.2, yes. 0.5 to 2.4. Is  24 that the one you're referring to?</p>

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<p style="text-align: right;">Page 478</p> <p>1 Q. Correct.</p> <p>2 A. Yes.</p> <p>3 Q. Go back to Cook and the</p> <p>4 confidence interval is to 3.4.</p> <p>5 A. Yes, I see that.</p> <p>6 Q. That's a mistake, is it not?</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 THE WITNESS: No, it's not.</p> <p>10 BY MR. TISI:</p> <p>11 Q. It isn't a mistake?</p> <p>12 A. That's not a mistake.</p> <p>13 Q. Okay. All right. Why is it</p> <p>14 not a mistake?</p> <p>15 A. Because, for the same</p> <p>16 reasons as the previous paper. So this</p> <p>17 was based on an adjustment, okay? The</p> <p>18 meta-analysis was based on unadjusted.</p> <p>19 So I'm sure you've probably</p> <p>20 gone through all this, and just as we had</p> <p>21 done with the first two articles, and my</p> <p>22 sense is that if there are differences</p> <p>23 that's probably the reason why, because</p> <p>24 the meta-analysis technique is based upon</p>	<p style="text-align: right;">Page 480</p> <p>1 Q. All right. Now, let's start</p> <p>2 with the -- let's start with the years of</p> <p>3 use.</p> <p>4 A. So --</p> <p>5 Q. That's Table 3. And he</p> <p>6 reports a 1.9 for the lowest exposure --</p> <p>7 a 1.86, right?</p> <p>8 A. That's correct.</p> <p>9 Q. And Cramer reports 1.9,</p> <p>10 correct? I mean I'm sorry, Huncharek</p> <p>11 reports it as 1.9?</p> <p>12 A. Yes.</p> <p>13 Q. And he reports a confidence</p> <p>14 interval, Cramer reports a confidence</p> <p>15 interval of 1.16?</p> <p>16 A. Yes.</p> <p>17 Q. And Dr. Huncharek reports it</p> <p>18 as a 1.2?</p> <p>19 A. Yes.</p> <p>20 Q. And those are different</p> <p>21 numbers, correct?</p> <p>22 MR. HEGARTY: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: They are</p>
<p style="text-align: right;">Page 479</p> <p>1 the -- the unadjusted numbers, rather</p> <p>2 than the adjusted published numbers.</p> <p>3 Q. Okay. Let's look at the</p> <p>4 Cramer, the Cramer paper. And Cramer is</p> <p>5 Tab 4 in your binder. He refers his</p> <p>6 frequency and month data on Table 2 on</p> <p>7 Page 353.</p> <p>8 A. Okay.</p> <p>9 Q. Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. Let's see if I can help you</p> <p>12 out here. This is the Cramer paper I put</p> <p>13 up.</p> <p>14 And he reports years of use</p> <p>15 on Table 3, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Okay. And he reports</p> <p>18 frequency of use on Table 2, correct?</p> <p>19 A. That's correct.</p> <p>20 Q. And as we talked about</p> <p>21 before, those are completely two</p> <p>22 different measurements, frequency and</p> <p>23 duration?</p> <p>24 A. That's correct.</p>	<p style="text-align: right;">Page 481</p> <p>1 different numbers.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Okay. The next one is the</p> <p>4 same. He reports the next category, 20</p> <p>5 to 30, is a 1.33 adjusted odds ratio,</p> <p>6 correct?</p> <p>7 A. That's correct.</p> <p>8 Q. And Dr. Huncharek reports it</p> <p>9 as a 1.3, correct?</p> <p>10 A. So, no, in fact, I'd like</p> <p>11 to -- I'd like to clarify that in terms</p> <p>12 of these being different numbers. They</p> <p>13 are -- they're for different calculations</p> <p>14 so you expect there to be different</p> <p>15 numbers.</p> <p>16 One is -- one is an adjusted</p> <p>17 odds ratio, the other is unadjusted odds</p> <p>18 ratio.</p> <p>19 So, you wouldn't expect them</p> <p>20 to be the same. Now, often when you do</p> <p>21 an adjustment it may change things a</p> <p>22 little bit. So it's unsurprising that</p> <p>23 the two are close. But it's not</p> <p>24 unsurprising that they are not exactly</p>



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<p style="text-align: right;">Page 482</p> <p>1 the same, because they are two different 2 calculations. 3 Okay. So same thing with 4 the previous papers that we've gone 5 through. Booth and Chang. It's -- it's 6 the -- it's the same -- it's the same 7 reason why the numbers aren't exactly the 8 same. Because they are different 9 calculations. 10 Q. Okay. Well, let's -- let's 11 ask -- let me talk about Gertig, the 12 fifth one. Now, in your chart you have 13 the lowest exposure category as 4 to 14 24 days, correct? 15 A. That's correct. 16 Q. That's one to six times a 17 week? 18 A. 4 to 24 -- 19 Q. Once -- or one times -- I'm 20 sorry. That's -- that's -- 21 A. Okay. 4 to 24 per month, 22 so -- I'm sorry, it's getting late in the 23 day, I can't even do my division. 24 4 to 24 per month, so it's</p>	<p style="text-align: right;">Page 484</p> <p>1 the whole textbook. 2 A. I'm sorry, Reference 3 is 3 Cooper. 4 Q. Are you looking at the -- 5 are you looking at the 2003 6 meta-analysis? 7 A. Yes. 8 Q. And then he cites -- I'm 9 sorry, but I think you're right. 10 Number -- then he cites 11 Number 9 for the literature retrieved was 12 performed by previously described 13 methods. That's Number 9. Do you see 14 that? 15 MR. HEGARTY: Objection to 16 form. 17 THE WITNESS: I'm sorry, let 18 me just find it. 19 BY MR. TISI: 20 Q. I'm sorry, but I think it 21 says Number 8? 22 A. Oh, okay. So -- 23 Q. I'm sorry, I can't read -- 24 A. That's all right. Actually</p>
<p style="text-align: right;">Page 483</p> <p>1 up to -- up to daily, less than daily. 2 Q. Okay. And -- but that's not 3 the lowest exposure category that is 4 reported in Gertig, is it? If you look 5 at Table 2. The lowest category is less 6 than one time a week. 7 A. Yes, that's correct. 8 Q. So like in Booth, they did 9 not -- he did not use the lowest exposure 10 category, right? 11 A. That's correct. 12 Q. And more importantly, 13 Doctor, he compared his methodology in 14 the methods section -- well, let me -- 15 you asked about the methodology he 16 employed. 17 If you go to the methodology 18 section of his paper, he really cites 19 three references. He goes -- if you go 20 to the methodology section, if you look 21 at it, he cites three papers. 22 The first one is Note 3, 23 which if you go in the back of the paper, 24 that's the Rothman textbook. He cites</p>	<p style="text-align: right;">Page 485</p> <p>1 I'm having a hard time. 2 Q. And it refers -- and 3 Reference Number 8 is a Cook paper which 4 is not a methodology paper at all, is it? 5 The Cook paper is a -- is the 6 case-control study we talked about 7 before. 8 MR. HEGARTY: Objection to 9 form. 10 THE WITNESS: That's -- so 8 11 is a misreference. 12 BY MR. TISI: 13 Q. Okay. And actually if you 14 look at -- if you look at the last one, 15 it says, "The statistical methods. The 16 data analysis was performed according to 17 a procedure described by Greenland." 18 Do you see that? 19 A. Yes. 20 Q. Okay. And that's Reference 21 Number 4? 22 A. Yes. 23 Q. Would it surprise you to 24 know that there is no 1996 Greenland</p>



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<p style="text-align: right;">Page 486</p> <p>1 article? I looked for it, I couldn't 2 find it anywhere. 3 MR. HEGARTY: Objection to 4 form. 5 BY MR. TISI: 6 Q. Do you know what that 7 article is? 8 A. I don't have it on me 9 personally. It's published in a journal 10 called Epidemiologic Reviews. 11 Q. Right. There is no 1996 12 article there, if I looked at it -- if I 13 looked at it. There is none. 14 A. Okay. Well, I -- 15 MR. HUDSON: Excuse me. 16 There's no question pending. 17 Sorry. 18 BY MR. TISI: 19 Q. Do you know what article 20 he's talking about? 21 A. I'd have to go look it up. 22 Q. Do any of these articles 23 tell you that -- how he is going to use 24 adjusted versus unadjusted numbers for</p>	<p style="text-align: right;">Page 488</p> <p>1 form. 2 THE WITNESS: I'm sorry, can 3 you repeat the question? 4 BY MR. TISI: 5 Q. Yes. 6 A. Yes. 7 Q. He doesn't -- he doesn't 8 describe what he did. That's the 9 whole -- that's the whole handbook that 10 he described. Do you know how big that 11 is? 12 MR. SILVER: Objection to 13 form. 14 MR. HUDSON: Objection to 15 form. 16 THE WITNESS: So there 17 are -- there are books on 18 meta-analysis. 19 BY MR. TISI: 20 Q. I understand that. 21 A. Yes. 22 Q. But it doesn't -- we talked 23 about the importance of replication 24 before. How is anybody supposed to</p>
<p style="text-align: right;">Page 487</p> <p>1 his meta-analysis? 2 MR. HUDSON: Objection to 3 form. 4 THE WITNESS: So Reference 5 3, the methods employed in this 6 analysis have been previously 7 described. So that's -- that's 8 very common in the literature, in 9 fact, it's almost encouraged by 10 journals to cite previous 11 publications where you describe 12 things so you don't have to keep 13 repeating yourself in order to 14 save space. So that's -- that's 15 quite common. 16 BY MR. TISI: 17 Q. Number 3 is actually a 18 Handbook of Research Synthesis. It's the 19 whole handbook. How is somebody supposed 20 to replicate what he did if he didn't say 21 what -- what he did? 22 MR. HEGARTY: Objection to 23 form. 24 MR. SILVER: Objection to</p>	<p style="text-align: right;">Page 489</p> <p>1 replicate what he did if he doesn't 2 describe what he did? 3 MR. SILVER: Objection to 4 form. 5 THE WITNESS: I just did. 6 Right in front of everybody 7 without even -- without even 8 looking at this cite. You know, 9 anyone who knows meta-analysis, I 10 was able to see -- I understand 11 what -- I understand exactly what 12 he did. 13 BY MR. TISI: 14 Q. Okay. Let me ask you this. 15 Does it show the weights that he gave to 16 each study? You talk about the 17 importance of determining what -- what 18 the weights were. 19 Remember we talked about the 20 fact that you can't -- you can't 21 replicate until you -- until you know 22 what weights he gave the studies? 23 MR. HEGARTY: Objection to 24 form.</p>

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<p style="text-align: right;">Page 490</p> <p>1 THE WITNESS: So the weights 2 are based on the variance. Okay. 3 So he describes the variance 4 formula. So that can go back and 5 be replicated. 6 BY MR. TISI: 7 Q. Where -- where is the 8 variance formula? 9 A. It's on Page 1956. 10 Q. Okay. And is it -- is it 11 that formula up at the top right-hand 12 corner? 13 A. So I believe so. I haven't 14 looked at meta-analyses in a long time. 15 But from my recollection is that the 16 weights are based upon the variance 17 formula and that's -- that's what's 18 provided. 19 Q. Now, going back to the 20 dose-response issue we talked about 21 before. He says that he looked at the 22 lowest exposure category for each study 23 group and the highest exposure category 24 for each study group, right? It's on --</p>	<p style="text-align: right;">Page 492</p> <p>1 A. That's correct. 2 Q. We talked about the fact 3 several times, frequency and duration are 4 the same, and we need to measure like 5 with like, right? 6 MR. HEGARTY: Objection to 7 form. 8 THE WITNESS: One is in 9 terms of frequency, the other's in 10 terms of duration rate. 11 BY MR. TISI: 12 Q. So my question is, how is 13 it -- how can you on a -- do a proper 14 meta-analysis combining frequency and 15 duration and calculate a relative risk 16 from that? You can't do that, can you? 17 MR. HEGARTY: Objection to 18 form. 19 THE WITNESS: So I'd have to 20 go through this and see whether 21 he's referring to one or the 22 other. 23 BY MR. TISI: 24 Q. Well, it looks like he</p>
<p style="text-align: right;">Page 491</p> <p>1 it's on Page 1958, first column. That's 2 what he says he did. I have put it up on 3 the screen. Right here, it says, "Seven 4 studies were included in the 5 dose-response relationship" -- 6 A. Okay. 7 Q. -- "stratified by the number 8 of talc applications per month." 9 A. Yes, I see that. 10 Q. "A comparison was made 11 across studies, using the lowest recorded 12 category and the highest exposure level." 13 A. That's correct. 14 Q. And from that he developed a 15 relative risk of 1.83 for the lowest 16 exposure group and a 1.21 for the highest 17 talc category. 18 A. Yes. 19 Q. Okay. Now, some of these 20 are measured in terms of frequency if you 21 look at the chart, right? 22 A. That's correct. 23 Q. Some are measured in terms 24 of duration, correct?</p>	<p style="text-align: right;">Page 493</p> <p>1 combined both, right? 2 MR. HEGARTY: Objection to 3 form. 4 THE WITNESS: I -- 5 BY MR. TISI: 6 Q. Does he indicate that he 7 looked at one or the other? 8 MR. HEGARTY: Objection to 9 form. 10 THE WITNESS: Okay. May I 11 read this? 12 BY MR. TISI: 13 Q. Sure. 14 A. Okay. 15 MR. TISI: We'll go off the 16 record. 17 THE WITNESS: So -- 18 MR. TISI: Go ahead, unless 19 you -- 20 THE WITNESS: I just need 21 like 20 more seconds. 22 BY MR. TISI: 23 Q. Okay. Go ahead. 24 A. Well, on the -- he's talking</p>



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<p style="text-align: right;">Page 494</p> <p>1 about number of talc applications. So  2 my -- I would assume that's the  3 frequency.  4 Q. It's like he used one  5 measure, but not the other.  6 A. His reference to this is  7 with regard to frequency.  8 Q. Okay. And do you know if he  9 did it by duration as well, and what he  10 found?  11 A. I'd have to read the  12 article.  13 Q. Well, if he combined  14 exposure categories, that would be an  15 improper methodology, wouldn't you agree?  16 MR. HEGARTY: Objection to  17 form.  18 THE WITNESS: Frequency  19 and --  20 BY MR. TISI:  21 Q. Duration.  22 A. -- duration.  23 Would it be improper?  24 Q. It's like with the pack</p>	<p style="text-align: right;">Page 496</p> <p>1 right?  2 A. That's correct.  3 Q. All right. So you  4 combine -- under the theory, you combine  5 like with like. You would not want to  6 combine pack years or number of years  7 smoked versus frequency of smoking,  8 correct?  9 MR. HUDSON: Objection to  10 form.  11 BY MR. TISI:  12 Q. Because there's a big  13 difference between somebody who smokes a  14 cigarette a day and somebody who smokes  15 three packs a day.  16 A. You can -- if you wanted to,  17 as an analyst, if you wanted to combine  18 frequency and duration, you can do that.  19 If that's --  20 Q. But you've got to tell  21 people that's what you're doing, right?  22 MR. HEGARTY: Objection to  23 form.  24 THE WITNESS: So that's --</p>
<p style="text-align: right;">Page 495</p> <p>1 years versus number of cigarettes  2 approach.  3 A. So -- so -- no, not  4 necessarily. I mean, like -- exactly,  5 right. So some people may use pack  6 years, I don't -- I don't really like it  7 as a form of exposure. But if you want  8 to do it, you can do it. It wouldn't be  9 my preferred way of measuring something.  10 Q. Actually, I was asking you a  11 slightly different question.  12 A. Yes.  13 Q. What I was asking you is,  14 would it be appropriate to combine pack  15 years with number of cigarettes per day  16 or per month in calculating relative  17 risk?  18 MR. HEGARTY: Objection to  19 form.  20 THE WITNESS: Pack years is  21 based upon both the frequency and  22 the duration.  23 BY MR. TISI:  24 Q. And one is just frequency,</p>	<p style="text-align: right;">Page 497</p> <p>1 if, for instance, the smoking app,  2 that's known. So pack years is a  3 measurement of frequency by  4 duration.  5 BY MR. TISI:  6 Q. All right. What about  7 number of -- number of years smoked.  8 You've seen articles like that. I smoked  9 30 years.  10 A. Yes, that's right.  11 Q. Would you ever combine "I've  12 smoked 30 years" with "I smoked eight  13 pack" -- "eight cigarettes a day per  14 month"?  15 A. That would be pack years.  16 Q. Right. Could you -- is that  17 even appropriate?  18 A. It's done. I mean people in  19 the literature --  20 Q. Is it appropriate?  21 Meta-analysis, under theories of  22 meta-analysis where you -- where you  23 combine like with like, is it appropriate  24 to combine frequency and duration?</p>

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<p style="text-align: right;">Page 498</p> <p>1 A. So if the -- let's say using 2 the smoking example, if you were doing a 3 meta-analysis of pack years, if that's 4 the way exposure information was in pack 5 years, then there's nothing wrong with 6 doing the meta-analysis of pack years. 7 Q. Pack years. Yeah. 8 A. That's correct. 9 Q. But would you combine that 10 with pack years versus number of 11 cigarettes a month? 12 If you had -- if you had a 13 group of studies that looked at, I smoked 14 five cigarettes a day for a month, and 15 you had a group of studies with that, and 16 you had another group of studies that 17 looked at pack years, would you take 18 those two studies and combine them 19 together and do a meta-analysis? 20 MR. HUDSON: Objection to 21 form. 22 BY MR. TISI: 23 Q. With those two different 24 variables?</p>	<p style="text-align: right;">Page 500</p> <p>1 A. So it -- I'd have to go 2 through -- I'd have to read the whole 3 thing. Okay. 4 Q. You haven't seen, when you 5 looked at this paper -- you looked at 6 this paper before you came in here today, 7 didn't you? 8 A. I've seen this paper, right. 9 Q. In fact, you refer to it 10 over and over and over again. You can't 11 tell me as you sit here today what 12 exposure categories he actually used, can 13 you? 14 MR. HUDSON: Objection to 15 form. 16 MR. HEGARTY: Objection. 17 THE WITNESS: So he used the 18 exposure categories that were 19 reported in the table. 20 BY MR. TISI: 21 Q. And some of them are 22 expressed in frequency, and some of them 23 are expressed in duration, right? 24 A. That's correct.</p>
<p style="text-align: right;">Page 499</p> <p>1 MR. HUDSON: Same objection. 2 THE WITNESS: If you had the 3 data on smoking years and you had 4 the data on pack years, and you 5 wanted to do a meta-analysis that 6 looked at both smoking years and 7 pack years and the data was 8 available. 9 BY MR. TISI: 10 Q. But you've got to tell 11 people what you've done, right? 12 A. Yes, of course. 13 Q. All he said was he -- by the 14 lowest exposure category and the highest 15 exposure -- exposure category, and you 16 don't know what categories he used, do 17 you? 18 A. So yeah, I just went through 19 that, right? 20 Q. Do you know whether he used 21 the -- in the Cramer study, do you know 22 whether he used the years or do you know 23 whether he used the number of 24 applications per month, what did he use?</p>	<p style="text-align: right;">Page 501</p> <p>1 Q. And those -- those two 2 things are apples and oranges. From -- 3 from standard point of view of 4 meta-analysis, frequency and duration are 5 two different things? 6 MR. HEGARTY: Objection, 7 form. 8 THE WITNESS: The -- in 9 terms of meta-analysis, you'd want 10 to do is combine all the data with 11 frequency, right? Combine that 12 data and then combine separately 13 all the data of duration. 14 BY MR. TISI: 15 Q. There is no indication that 16 that was done as two separate analyses, 17 right? 18 A. I would -- well, I'd really 19 have to look at this closely. You know, 20 I think just -- 21 Q. Well, did you look at it 22 closely before you -- 23 A. I have -- 24 Q. Well, let me -- let me ask</p>



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<p>1 you this.</p> <p>2 A. Yes, yes.</p> <p>3 Q. Did you look at it closely</p> <p>4 before you sent it to the FDA when they</p> <p>5 were considering a -- when they were</p> <p>6 considering putting a warning for talc</p> <p>7 on -- on women and you were telling them</p> <p>8 there was no dose-response? Did you --</p> <p>9 did you look at that?</p> <p>10 MR. HEGARTY: Objection to</p> <p>11 form.</p> <p>12 THE WITNESS: It was based</p> <p>13 on a published data. And I regard</p> <p>14 Dr. Huncharek as a credible</p> <p>15 scientist.</p> <p>16 BY MR. TISI:</p> <p>17 Q. Did you look -- did you</p> <p>18 personally look at the data?</p> <p>19 A. I --</p> <p>20 Q. You knew -- let me just --</p> <p>21 A. I had not gone back. And</p> <p>22 this exercise that we're currently doing</p> <p>23 right now, I have not done this.</p> <p>24 Q. Okay. Well, let me -- let</p>	<p>1 Q. Okay. And Dr. Epstein was</p> <p>2 asking that all you needed to do was put</p> <p>3 on a little bottle and say increasing --</p> <p>4 putting a -- applying talc in your</p> <p>5 underwear may -- may cause ovarian</p> <p>6 cancer, right? That's what he was asking</p> <p>7 to have happen, right?</p> <p>8 MR. HEGARTY: Objection to</p> <p>9 form.</p> <p>10 MR. HUDSON: Objection to</p> <p>11 form.</p> <p>12 MR. SILVER: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: I'd have to go</p> <p>15 back and read it.</p> <p>16 BY MR. TISI:</p> <p>17 Q. Okay.</p> <p>18 A. Okay.</p> <p>19 Q. But the stakes were pretty</p> <p>20 high, right? That's a big -- that's a</p> <p>21 big issue. It's a big public health</p> <p>22 issue, right?</p> <p>23 MR. SILVER: Objection.</p> <p>24 MR. HUDSON: Objection to</p>
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<p>1 me be absolutely clear.</p> <p>2 The stakes for women, if</p> <p>3 there is a risk, ovarian cancer kills,</p> <p>4 correct?</p> <p>5 MR. SILVER: Objection.</p> <p>6 MR. HUDSON: Objection to</p> <p>7 form.</p> <p>8 THE WITNESS: That's</p> <p>9 correct.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Ovarian cancer -- ovarian</p> <p>12 cancer is the seventh cause of cancer</p> <p>13 death in women overall. And you've</p> <p>14 mentioned that, correct?</p> <p>15 MR. HUDSON: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: It's a -- it's</p> <p>18 a very fatal disease.</p> <p>19 BY MR. TISI:</p> <p>20 Q. High mortality, correct?</p> <p>21 A. That's correct.</p> <p>22 Q. And you want to get your</p> <p>23 data right?</p> <p>24 A. That's correct.</p>	<p>1 form.</p> <p>2 THE WITNESS: Is what a big</p> <p>3 public health issue?</p> <p>4 BY MR. TISI:</p> <p>5 Q. Whether or not talc causes</p> <p>6 ovarian cancer.</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 BY MR. TISI:</p> <p>10 Q. If it does, that's a big</p> <p>11 deal?</p> <p>12 A. If it does.</p> <p>13 Q. Right. And what he was</p> <p>14 asking was, let's put on the bottle a</p> <p>15 warning for women not to use talc in</p> <p>16 their genital area, right?</p> <p>17 MR. SILVER: Objection to</p> <p>18 form.</p> <p>19 MR. HEGARTY: Objection to</p> <p>20 form.</p> <p>21 THE WITNESS: I guess you</p> <p>22 are paraphrasing that. So --</p> <p>23 BY MR. TISI:</p> <p>24 Q. Well, let's look at exactly</p>



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<p style="text-align: right;">Page 506</p> <p>1 what he was asking to be done. Let's go 2 back to the actual Citizen's Petition. 3 Once the -- if you look at 4 the very beginning it says, he filed a -- 5 on Page 3 of the Citizen's Petition, 6 Page 6 of 9, 166. 7 A. Right. 8 Q. Introduction. 9 1998. He asked the Food and 10 Drug Administration to look and say, "The 11 petition requests the Food and Drug 12 Administration require that all talc 13 products bear a label warning such as: 14 Frequent application of talcum powder in 15 the female genital area substantially 16 increases the risk of ovarian cancer." 17 Do you see that? 18 A. Yes. 19 Q. Okay. Now, that's -- if 20 that is true, if the science is true, 21 okay, that would be an important thing 22 for women to know. 23 MR. SILVER: Objection to 24 form.</p>	<p style="text-align: right;">Page 508</p> <p>1 Q. And if there is a risk and 2 women use it, that's a pretty serious 3 thing, correct? 4 MR. HEGARTY: Objection to 5 form. 6 MR. HUDSON: Objection to 7 form. 8 THE WITNESS: If it -- if 9 talcum powder causes ovarian 10 cancer, that would be a serious 11 thing. 12 BY MR. TISI: 13 Q. And this -- the question 14 that you were asked to address here was a 15 serious question. 16 A. Yes. 17 Q. And one of the things that 18 you made a big deal about pointing out to 19 the -- to the FDA was there's no 20 dose-response, right? 21 And, in fact, you referred 22 them to the Table 5 in -- Table 2 in the 23 2003 Huncharek meta-analysis, correct? 24 MR. HEGARTY: Objection to</p>
<p style="text-align: right;">Page 507</p> <p>1 MR. HUDSON: Objection to 2 form. 3 BY MR. TISI: 4 Q. The stakes are pretty high, 5 right? 6 MR. SILVER: Objection to 7 form. 8 MR. HEGARTY: Same 9 objection. 10 THE WITNESS: Can you repeat 11 the question? 12 BY MR. TISI: 13 Q. Yeah. We're not talking 14 about, you know, ripping a cuticle, we're 15 talking about ovarian cancer here, right? 16 A. Yeah, that's correct. 17 Q. And we are talking about a 18 household product that people have -- 19 that people can buy in the Kmart, right? 20 MR. HEGARTY: Objection to 21 form. 22 THE WITNESS: It's a -- it's 23 a common product, that's correct. 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 509</p> <p>1 form. 2 THE WITNESS: It is 3 referred, that's correct. 4 BY MR. TISI: 5 Q. And not only did you do 6 that, but then you published that chart 7 in 2011, while the petition was still 8 pending, correct? 9 MR. HEGARTY: Objection to 10 form. 11 BY MR. TISI: 12 Q. Because it wasn't denied 13 until 2015. 14 A. Okay. So I don't have 15 knowledge of when it was -- 16 Q. He published it again. And 17 so this is an important issue, right? 18 MR. HEGARTY: Objection to 19 form. 20 THE WITNESS: I'm sorry, 21 which important issue? The talcum 22 powder? Yes. Yes. 23 BY MR. TISI: 24 Q. Yeah. And whether or not</p>



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<p style="text-align: right;">Page 510</p> <p>1 there is a dose-response is an 2 important -- would be an important factor 3 to consider in the causation analysis as 4 to whether or not Dr. Epstein was right 5 or whether Dr. Huncharek was right? 6 MR. HUDSON: Objection to 7 form. 8 THE WITNESS: So I don't 9 know -- I don't know if it's a 10 matter of Epstein versus 11 Huncharek. It's an issue, a 12 dose-response issue, right. 13 BY MR. TISI: 14 Q. Right. And you -- I mean 15 you and I are sitting here across a table 16 in 2018 looking at this data. Did you 17 look at the data and look at how he got 18 that data knowing it was important in 19 2000 -- in 2009 when that issue was 20 pending before the FDA? 21 MR. HEGARTY: Objection to 22 form. 23 MR. HUDSON: Objection to 24 form.</p>	<p style="text-align: right;">Page 512</p> <p>1 form. Asked and answered. 2 THE WITNESS: I think you 3 should -- I'd have to go through 4 this entire thing in order to 5 answer that question. But he 6 would best be able to answer that 7 question. 8 BY MR. TISI: 9 Q. Well, you co-signed this 10 paper, both the one that went to the FDA 11 and the one that was published in 2011. 12 Did you ask him? 13 MR. HEGARTY: Objection to 14 form. 15 THE WITNESS: Did I ask him 16 what? 17 BY MR. TISI: 18 Q. How did you come up with 19 this dose-response data? 20 A. It's -- it's in the paper. 21 Q. I didn't -- 22 A. Yes. 23 Q. -- did you ask him, did you 24 discuss it with him?</p>
<p style="text-align: right;">Page 511</p> <p>1 THE WITNESS: So that data 2 was published. It was published 3 in a peer-reviewed paper. And so 4 I rely on it. 5 BY MR. TISI: 6 Q. Okay. Did you -- did you 7 look at it carefully? Because if you 8 looked at it carefully, there are some 9 questions that we've talked about here 10 today that need to be answered, correct? 11 MR. HUDSON: Objection to 12 form. 13 MR. HEGARTY: Objection to 14 form. 15 THE WITNESS: I think we did 16 answer them. 17 BY MR. TISI: 18 Q. Do you know whether or not 19 he combined like with like, frequency and 20 duration? Do you know that from this 21 study? 22 MR. HEGARTY: Objection to 23 form. 24 MR. HUDSON: Objection to</p>	<p style="text-align: right;">Page 513</p> <p>1 MR. HEGARTY: Objection to 2 form. 3 THE WITNESS: So, no, I 4 didn't discuss it with him. 5 BY MR. TISI: 6 Q. Okay. Now, you also make 7 the point that a few -- that few authors 8 mention the lack of dose-response in 9 their papers when they're looking at -- 10 do you see that, in your PCPC? 11 If you go to Page 24 of what 12 you sent to the FDA. 13 MR. HEGARTY: Objection to 14 form. 15 BY MR. TISI: 16 Q. Exhibit 25. You say, "Few 17 authors directly address the above noted 18 lack of evidence of dose-response." Do 19 you see that? 20 A. Yeah, I see that. 21 Q. In fact, there are many of 22 the authors address that issue and say 23 that they see evidence of dose-response, 24 correct?</p>



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<p style="text-align: right;">Page 514</p> <p>1 MR. HEGARTY: Objection to 2 form. 3 MR. HUDSON: Objection to 4 form. 5 THE WITNESS: I'd have to go 6 through every single article to 7 look at them. 8 BY MR. TISI: 9 Q. Well, why don't you look at 10 Harlow in your binder, fifth study in 11 your binder. 12 MR. SILVER: Which Harlow is 13 this? 14 MR. TISI: I'll find it for 15 you in a minute. 16 BY MR. TISI: 17 Q. Can you go to Page 22. 18 Actually we need to move on because I 19 can't find my copy of the paper right 20 now. 21 Would it surprise you when 22 they looked at trends of dose-response, 23 that there was evidence that many of 24 these -- or several of these authors</p>	<p style="text-align: right;">Page 516</p> <p>1 BY MR. TISI: 2 Q. They did report that, 3 correct? 4 A. I'm sorry, where was the 5 Harlow article? 6 Q. It's in your binder. Let's 7 look at Chang. Let's see if we can do 8 that. That's a little bit easier. I 9 have that at my fingertips. 10 A. Okay. 11 Q. At Chang, on Page 2400. 12 Page 5 of 6, left-hand column, it says, 13 "Duration as a continuous variable 14 indicated that risk may increase with 15 increasing years by talc exposure." 16 Do you see that? 17 MR. HUDSON: Sorry. Can you 18 tell us the page again? 19 MR. TISI: Page 2400. 20 BY MR. TISI: 21 Q. Look at the bottom left-hand 22 corner. Do you see right at the bottom, 23 second sentence, "Duration as a 24 continuous variable indicated the risk</p>
<p style="text-align: right;">Page 515</p> <p>1 talked about dose-response -- 2 MR. HEGARTY: Objection to 3 form. 4 BY MR. TISI: 5 Q. -- increasing with time? 6 A. So some did, some didn't. 7 Q. You don't note that in the 8 FDA, did you? 9 MR. HUDSON: Objection to 10 form. 11 BY MR. TISI: 12 Q. On Page 22 of the Harlow 13 article, the authors state, "With monthly 14 frequency was considered as a continuous 15 variable. The logistic model of Chi 16 Square linear test was 4.06, indicating 17 the risk of ovarian cancer increased 18 significantly with increasing frequency 19 of applications per month." 20 A. Yes. 21 MR. HUDSON: Objection to 22 form. There's no question 23 pending. 24 THE WITNESS: Sorry. Okay.</p>	<p style="text-align: right;">Page 517</p> <p>1 may increase with increasing years of 2 talc exposure. These results are similar 3 to the findings of Cramer, Harlow, Harlow 4 and Weiss, Cook, Whittemore, in which 5 trends of duration of frequency were not 6 significant." 7 A. Yes. 8 Q. So they're reporting there 9 is a trend in favor of dose-response, 10 correct? 11 MR. HEGARTY: Objection to 12 form. 13 MR. HUDSON: Objection to 14 form. 15 THE WITNESS: No. They are 16 reporting that trends were not 17 significant. 18 BY MR. TISI: 19 Q. They said, "Duration as a 20 continuous variable indicated that risk 21 may increase with years of talc 22 exposure," correct? 23 A. That's what it says. 24 Q. Okay. Now, the next thing</p>

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<p style="text-align: right;">Page 518</p> <p>1 that you mention, first of all -- and in  2 your report you mention that there is  3 evidence of an inverse relationship  4 between dose and cancer, correct, that  5 the longer the dose, the longer the  6 application --  7 A. I'm sorry. But can we go  8 back to this article here, Chang?  9 Q. Mm-hmm. Yeah.  10 A. I'm looking at this data.  11 And it looks like there's an inverse  12 trend.  13 Q. What could explain an  14 inverse trend? There are reasons for  15 that, right?  16 MR. HEGARTY: Objection to  17 form.  18 BY MR. TISI:  19 Q. Inverse trend, have you ever  20 heard of survivor bias?  21 A. I'll tell you the most  22 probable reason would be simply recall  23 bias.  24 Q. Did you explore survival</p>	<p style="text-align: right;">Page 520</p> <p>1 MR. SILVER: Objection to  2 form.  3 THE WITNESS: You can -- you  4 can speculate on the data. The  5 only thing I can say with regard  6 to the trend that you were  7 pointing out previously, that the  8 data show a trend, is that -- you  9 pointed specifically to this  10 article, is that the trend is  11 inverse. So there is an inverse  12 trend.  13 BY MR. TISI:  14 Q. And the --  15 A. It's the opposite of what  16 you were just suggesting; isn't that  17 true?  18 Q. No. I'm asking you the  19 questions, Doctor. Aren't there reasons  20 why that might be the case? Did you  21 explore what reasons might that be?  22 A. There are so many reasons  23 why you may get the results in a study.  24 It could be bias. It could be</p>
<p style="text-align: right;">Page 519</p> <p>1 bias? You know what that is, right?  2 A. So how would survival bias  3 play? I don't see it.  4 Q. You don't see it. Did you  5 explore any biases that might explain a  6 dose-response relationship that was  7 inverse?  8 A. I'm just answering --  9 answering your question.  10 Q. No, I'm asking you --  11 A. Okay.  12 Q. -- did you explore it? When  13 you observed an inverse relationship, did  14 you explore reasons why that might be?  15 A. Did I explore -- why would  16 survival bias -- I wouldn't understand  17 how that would be. But if it's a bias,  18 it's a bias, right? That would --  19 Q. Well, but -- no, a bias  20 is -- a bias is -- some biases would  21 suggest a dose-response. Not every --  22 not every -- not every reaction is  23 linear, for example. Some could be  24 U-shaped, right?</p>	<p style="text-align: right;">Page 521</p> <p>1 confounding. I can't speak for this  2 particular study.  3 Q. I'm asking you, when you did  4 your study, when you -- when you --  5 A. I didn't do a study, yeah.  6 Q. Well, when you reported  7 these to the FDA, did you say, "And we  8 explored reasons why we thought there  9 would be an inverse relationship"?  10 MR. HUDSON: Objection to  11 form.  12 BY MR. TISI:  13 Q. Some of them consistent with  14 causation, some of them not.  15 A. That -- it's beyond --  16 that's like -- that would be like a  17 classroom exercise. Simply reported what  18 the results are. Are there trends --  19 Q. You drew conclusions --  20 MR. HUDSON: Excuse me. Can  21 he finish his --  22 BY MR. TISI:  23 Q. You drew conclusions from  24 those. You said that there was inverse</p>



<p style="text-align: right;">Page 522</p> <p>1 relationship and, therefore, no 2 dose-response, correct? 3 A. So you're talking about this 4 particular study, is that there is an 5 inverse relationship -- 6 Q. No, I'm talking about -- I'm 7 talking about the meta-analysis that 8 Dr. -- that Dr. Huncharek did -- 9 A. Yes. 10 Q. -- and you referred the FDA 11 to? 12 A. That's correct. 13 Q. Right. And you made the 14 comment that that inverse relationship 15 suggested no dose-response, correct? 16 A. In this particular Chang 17 article -- 18 Q. No. In Dr. -- 19 meta-analysis -- in Dr. Huncharek's 20 meta-analysis? 21 A. That's the way he calculated 22 it. 23 Q. All right. And my question 24 is, did you explore reasons as to why</p>	<p style="text-align: right;">Page 524</p> <p>1 A. I see that. 2 Q. -- "in which talc particles 3 could induce ovarian tumors." 4 Do you see that? 5 A. Yes. 6 Q. And you go on to say -- and 7 this is the point that I want to just 8 stop at right here. It says, "A number 9 of investigators" -- next paragraph. "A 10 number of investigators initially 11 implicated talc products as possible 12 carcinogens since prior to the early 13 1970s some talc products contained small 14 amounts of asbestos (Rohl 1976)." That's 15 that same reference that we talked about 16 before, right? 17 A. Yes. 18 MR. SILVER: Objection. Not 19 read correctly. 20 THE WITNESS: Sorry. 21 BY MR. TISI: 22 Q. "A number of investigators 23 initially implicated talc products as 24 possible carcinogens since prior to the</p>
<p style="text-align: right;">Page 523</p> <p>1 that would be the case? 2 MR. HUDSON: Objection to 3 form. 4 THE WITNESS: Did I explore 5 reasons? I still don't understand 6 the question. What reasons am 7 I -- the meta-analysis is to 8 report on the data. 9 BY MR. TISI: 10 Q. Let's talk about lack of 11 biologic plausibility. Let me just stop 12 for a moment there. Actually, let me 13 just move on. 14 Lack of biologic 15 plausibility. One of the arguments you 16 made on page -- of your report to the FDA 17 is that there was no evidence of biologic 18 plausibility. And if you go to Page 25. 19 You make that point. You start out with, 20 "An additional limitation on existing 21 literature dealing with proposed ovarian 22 cancer association is the lack of any 23 known biologically plausible 24 mechanism" --</p>	<p style="text-align: right;">Page 525</p> <p>1 early 1970s, some talc products contained 2 small amounts of asbestos fibers (Rohl 3 1976)." 4 Did I read that correctly? 5 A. Yes. 6 Q. Do you remember when I 7 talked about -- I asked you before 8 whether or not Rohl referred to the first 9 part and second part of that sentence in 10 your prior study. This is what Rohl 11 stands for, correct? 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: I'm sorry. 15 Can you repeat that. 16 BY MR. TISI: 17 Q. Yes. Well let me keep 18 going? 19 A. Okay. 20 Q. "Clearly such products could 21 represent a carcinogenic risk secondary 22 to asbestos contamination." 23 Correct? 24 MR. HEGARTY: Objection to</p>



<p style="text-align: right;">Page 526</p> <p>1 form.</p> <p>2 THE WITNESS: That's what it</p> <p>3 says.</p> <p>4 BY MR. TISI:</p> <p>5 Q. Would you agree with me that</p> <p>6 if talc contains asbestos, it has --</p> <p>7 there is a biologically plausible</p> <p>8 mechanism by which talcum powder products</p> <p>9 can cause ovarian cancer?</p> <p>10 MR. HEGARTY: Objection to</p> <p>11 form.</p> <p>12 MR. HUDSON: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: So it's my</p> <p>15 understanding it doesn't contain</p> <p>16 asbestos.</p> <p>17 BY MR. TISI:</p> <p>18 Q. If it did, you're saying,</p> <p>19 "Clearly, such products if they contain</p> <p>20 asbestos, could possibly represent a</p> <p>21 carcinogenic risk secondary to asbestos</p> <p>22 contamination."</p> <p>23 Correct?</p> <p>24 MR. HEGARTY: Objection to</p>	<p style="text-align: right;">Page 528</p> <p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And so you are</p> <p>4 further emphasizing the point that if</p> <p>5 there is asbestos in -- it is asbestos,</p> <p>6 asbestos is the problem?</p> <p>7 MR. HUDSON: Objection to</p> <p>8 form.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Right?</p> <p>11 A. So, no.</p> <p>12 Q. You are not saying that?</p> <p>13 A. It's -- it's a general</p> <p>14 statement.</p> <p>15 Q. Okay. And then it goes on</p> <p>16 to say, "But since the early 1970s, the</p> <p>17 relevant industries voluntarily</p> <p>18 eliminated asbestos from contamination</p> <p>19 from talc products."</p> <p>20 Do you see that?</p> <p>21 A. Yes, I do.</p> <p>22 Q. And there is no reference</p> <p>23 for that, again. Was that an assumption</p> <p>24 on your part?</p>
<p style="text-align: right;">Page 527</p> <p>1 form.</p> <p>2 BY MR. TISI:</p> <p>3 Q. That's what you say?</p> <p>4 A. That's what's said, right.</p> <p>5 Q. Right. And that's what you</p> <p>6 said correct?</p> <p>7 A. I think that needs to be</p> <p>8 clarified.</p> <p>9 Q. No. That's what you said?</p> <p>10 A. Yes, but let me interpret</p> <p>11 it.</p> <p>12 Q. Well, let me -- let me --</p> <p>13 I'm not going to interpret it because I'm</p> <p>14 going to go on to the next sentence.</p> <p>15 A. Okay.</p> <p>16 Q. I'll ask you to interpret it</p> <p>17 in a second because let's look at it in</p> <p>18 context.</p> <p>19 A. Okay.</p> <p>20 Q. "It should be pointed out</p> <p>21 that in no way implicates talc" -- "talc</p> <p>22 as a toxin since the problematic</p> <p>23 constituents of such products was the</p> <p>24 asbestos fibers, not talc."</p>	<p style="text-align: right;">Page 529</p> <p>1 MR. HEGARTY: Objection to</p> <p>2 form.</p> <p>3 THE WITNESS: So this is --</p> <p>4 I don't know if it's an assumption</p> <p>5 on my part. I think it's</p> <p>6 something that has been well</p> <p>7 accepted in the literature.</p> <p>8 BY MR. TISI:</p> <p>9 Q. Do you know what -- can you</p> <p>10 point to me a single reference in the</p> <p>11 medical literature, one, which shows</p> <p>12 there is no asbestos in talc, talcum</p> <p>13 powder products, since 1976?</p> <p>14 A. I can't point to a single</p> <p>15 reference in literature that does show</p> <p>16 it.</p> <p>17 Q. Okay. I'm going to ask you</p> <p>18 to -- it says here, "The relevant</p> <p>19 industries voluntarily eliminated</p> <p>20 asbestos." You used the word</p> <p>21 "elimination," right?</p> <p>22 A. I'm sorry. Where are we?</p> <p>23 Q. The first sentence of that</p> <p>24 paragraph, elimination.</p>



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<p>1 A. Yes, I see that.</p> <p>2 Q. It was your assumption that</p> <p>3 asbestos was eliminated from talcum</p> <p>4 powder products since the 1970s?</p> <p>5 A. I see that.</p> <p>6 Q. If there was any talc in any</p> <p>7 of these products, would that provide a</p> <p>8 biologically plausible mechanism which</p> <p>9 would explain the increased risk seen in</p> <p>10 the epidemiology studies?</p> <p>11 MR. HEGARTY: Objection to</p> <p>12 form.</p> <p>13 MR. SILVER: Chris, you may</p> <p>14 want to look at that question.</p> <p>15 MR. TISI: Let me rephrase</p> <p>16 the question, because my learned</p> <p>17 counsel at the end --</p> <p>18 THE WITNESS: Okay.</p> <p>19 BY MR. TISI:</p> <p>20 Q. If there were talc in</p> <p>21 asbestos, if your assumption was -- if</p> <p>22 there was asbestos in talcum powder</p> <p>23 products, and your assumption was wrong,</p> <p>24 then there is a biologically plausible</p>	<p>1 THE WITNESS: So -- so --</p> <p>2 actually not true because first</p> <p>3 I'm not sure what increased</p> <p>4 relative risk that you're</p> <p>5 referring to, because the --</p> <p>6 BY MR. TISI:</p> <p>7 Q. Let's take that question --</p> <p>8 take that out of the question.</p> <p>9 A. Okay.</p> <p>10 Q. That would be a biologically</p> <p>11 plausible mechanism which talcum powder</p> <p>12 products would cause cancer?</p> <p>13 MR. SILVER: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: So can you</p> <p>16 repeat it? I'm still not sure.</p> <p>17 BY MR. TISI:</p> <p>18 Q. Yes. You do not want</p> <p>19 asbestos in talcum powder products,</p> <p>20 correct?</p> <p>21 A. That's correct.</p> <p>22 Q. Why?</p> <p>23 A. Because when I'm getting</p> <p>24 talcum powder products, I want talcum</p>
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<p>1 mechanism, you would agree, by which</p> <p>2 talcum powder products can cause ovarian</p> <p>3 cancer?</p> <p>4 MR. HUDSON: Objection to</p> <p>5 form.</p> <p>6 MR. SILVER: Objection to</p> <p>7 form.</p> <p>8 BY MR. TISI:</p> <p>9 Q. Your whole premise here --</p> <p>10 let me rephrase the question.</p> <p>11 A. Yes.</p> <p>12 Q. Your whole premise here was</p> <p>13 that talcum powder products do not</p> <p>14 contain asbestos, correct?</p> <p>15 A. That's correct.</p> <p>16 Q. That had been eliminated,</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. And if that was shown to not</p> <p>20 be true, there would be a biologically</p> <p>21 plausible mechanism which would explain</p> <p>22 the increased relative risk, true?</p> <p>23 MR. SILVER: Objection to</p> <p>24 form.</p>	<p>1 powder.</p> <p>2 Q. And you don't want asbestos?</p> <p>3 A. That's correct.</p> <p>4 Q. Why don't you want asbestos?</p> <p>5 A. Well, asbestos is a</p> <p>6 carcinogen, but it doesn't necessarily</p> <p>7 mean that if -- if asbestos was present</p> <p>8 in talcum powder, I'd want to set up a</p> <p>9 study to determine whether asbestos and</p> <p>10 talcum powder were a cause of ovarian</p> <p>11 cancer.</p> <p>12 Q. Do you know that asbestos</p> <p>13 has been characterized by IARC as a cause</p> <p>14 of ovarian cancer?</p> <p>15 MR. HUDSON: Objection to</p> <p>16 form.</p> <p>17 MR. SILVER: Objection to</p> <p>18 form.</p> <p>19 THE WITNESS: I am aware</p> <p>20 that IARC has looked at it, that's</p> <p>21 correct.</p> <p>22 BY MR. TISI:</p> <p>23 Q. And has concluded that</p> <p>24 asbestos is a carcinogen for ovarian</p>

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<p>1 cancer?</p> <p>2 MR. HUDSON: Objection to</p> <p>3 form.</p> <p>4 THE WITNESS: In an</p> <p>5 occupational setting.</p> <p>6 BY MR. TISI:</p> <p>7 Q. Of ovarian cancer?</p> <p>8 A. Yes.</p> <p>9 Q. How do you get cancer -- how</p> <p>10 do you get ovarian cancer in an</p> <p>11 occupational setting?</p> <p>12 A. Through dealing with mining,</p> <p>13 milling, paper products, secondary</p> <p>14 exposures.</p> <p>15 Q. Okay. So you can get it in</p> <p>16 your -- are you suggesting that a</p> <p>17 biologically plausible mechanism is</p> <p>18 inhaling asbestos?</p> <p>19 MR. HEGARTY: Objection to</p> <p>20 form.</p> <p>21 MR. SILVER: Objection to</p> <p>22 form.</p> <p>23 BY MR. TISI:</p> <p>24 Q. For ovarian cancer?</p>	<p>1 want asbestos in your talcum powder</p> <p>2 products?</p> <p>3 A. That's correct.</p> <p>4 Q. C, we know asbestos is a</p> <p>5 carcinogen, correct?</p> <p>6 A. It is a carcinogen for lung</p> <p>7 cancer mesothelioma.</p> <p>8 Q. And you also know that it is</p> <p>9 a carcinogen for ovarian cancer. You</p> <p>10 know that from IARC, correct?</p> <p>11 MR. SILVER: Objection to</p> <p>12 form.</p> <p>13 MR. HEGARTY: Objection to</p> <p>14 form.</p> <p>15 THE WITNESS: So I know IARC</p> <p>16 has looked at it. But that</p> <p>17 doesn't necessarily mean that I</p> <p>18 would come to the same conclusion.</p> <p>19 BY MR. TISI:</p> <p>20 Q. Well, that would provide a</p> <p>21 biologically plausible mechanism for</p> <p>22 ovarian cancer in talcum powder products</p> <p>23 if the talcum powder products contained</p> <p>24 asbestos?</p>
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<p>1 A. I'm sorry. What was that?</p> <p>2 Q. Is it a biologically</p> <p>3 plausible mechanism for ovarian cancer to</p> <p>4 inhale asbestos?</p> <p>5 MR. SILVER: Same objection.</p> <p>6 THE WITNESS: I don't know.</p> <p>7 BY MR. TISI:</p> <p>8 Q. Okay. So my question is --</p> <p>9 back up. Let's back up a little bit.</p> <p>10 A. Okay.</p> <p>11 Q. A, we can agree that you</p> <p>12 made an assumption that there is no</p> <p>13 asbestos in talcum powder products,</p> <p>14 correct?</p> <p>15 MR. SILVER: Objection to</p> <p>16 form.</p> <p>17 MR. HEGARTY: Objection to</p> <p>18 form.</p> <p>19 THE WITNESS: Since -- since</p> <p>20 that time period, that's correct.</p> <p>21 BY MR. TISI:</p> <p>22 Q. Since 1970s?</p> <p>23 A. Right.</p> <p>24 Q. B, we can agree we don't</p>	<p>1 MR. SILVER: Objection to</p> <p>2 form.</p> <p>3 MR. HUDSON: Objection to</p> <p>4 form.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Correct?</p> <p>7 A. So -- what? I'm sorry.</p> <p>8 Q. It would provide a</p> <p>9 biologically plausible explanation for</p> <p>10 talcum powder products causing ovarian</p> <p>11 cancer.</p> <p>12 MR. HUDSON: Objection to</p> <p>13 form.</p> <p>14 MR. SILVER: Objection to</p> <p>15 form.</p> <p>16 THE WITNESS: So we've</p> <p>17 talked about this. It's my</p> <p>18 opinion that it doesn't cause</p> <p>19 ovarian cancer.</p> <p>20 BY MR. TISI:</p> <p>21 Q. I'm not asking -- let's --</p> <p>22 put aside -- it was your opinion that</p> <p>23 talcum powder products, there is no</p> <p>24 biologic plausibility because talcum</p>

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<p style="text-align: right;">Page 538</p> <p>1 powder products do not contain asbestos.  2 That's what that says here?  3 A. That's one of the reasons,  4 yes.  5 Q. Right. Now, if you are  6 wrong and talcum powder products did  7 contain asbestos, they would in fact be a  8 biologically plausible mechanism, true?  9 MR. HEGARTY: Objection to  10 form.  11 MR. SILVER: Objection to  12 form.  13 MR. HEGARTY: Asked and  14 answered.  15 THE WITNESS: It -- no, not  16 necessarily. I mean, it would  17 depend upon the route of exposure.  18 Asbestos is a carcinogen. Don't  19 get me wrong. It is a cause of  20 mesothelioma. It's a cause of  21 lung cancer.  22 I think that's well  23 described.  24 But in order to determine</p>	<p style="text-align: right;">Page 540</p> <p>1 MR. HEGARTY: Objection to  2 form.  3 BY MR. TISI:  4 Q. In any of your -- no, you  5 know, in any of your studies, over the  6 past 20 years when you've been publishing  7 in the medical literature, when you've  8 been writing these reports, did you ever  9 inquire to anybody, you know something,  10 we need to figure out whether there is  11 anything else in this bottle that could  12 be a potential carcinogen?  13 MR. HEGARTY: Objection.  14 BY MR. TISI:  15 Q. Do you ever ask that  16 question?  17 MR. HEGARTY: Objection to  18 form.  19 THE WITNESS: I'm just not  20 sure why are we asking that  21 question.  22 So my --  23 BY MR. TISI:  24 Q. Because --</p>
<p style="text-align: right;">Page 539</p> <p>1 whether it is a cause of ovarian  2 cancer, you'd have to look at a  3 wide variety of literature. You'd  4 have to have epidemiological  5 studies. You'd have to do animal  6 experiments. You'd have to think  7 of mechanisms as how that would  8 occur.  9 So I couldn't say that if  10 asbestos was theoretically in  11 talcum powder, that it would be a  12 mechanism for causing ovarian  13 cancer, which I don't think is  14 associated with talcum powder.  15 BY MR. TISI:  16 Q. Do you know what talcum --  17 when we look at the bottle, do you know  18 what's in that bottle? The bottle -- if  19 you go to Kmart today, and you buy  20 Johnson's Baby Powder, talcum powder --  21 A. Yes.  22 Q. -- have you done any  23 research as to what is actually in that  24 bottle?</p>	<p style="text-align: right;">Page 541</p> <p>1 A. So my --  2 Q. Let me provide you an  3 answer.  4 MR. HUDSON: Let him finish  5 his answer.  6 BY MR. TISI:  7 Q. Let me provide -- I thought  8 you asked the question, you're not sure  9 why I'm asking that question.  10 MR. HUDSON: Let him finish  11 his answer.  12 THE WITNESS: Okay. You're  13 asking me whether talcum powder  14 is -- talcum powder or the  15 product, the talcum powder -- in  16 fact, that's the way IARC even  17 describes it, is talc-based  18 powders.  19 Okay. So talc-based powders  20 includes talc. I don't know  21 whether it has fragrance or not.  22 But it's the -- in fact, the way  23 the questions were even asked in  24 epidemiologic studies, most of</p>



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<p style="text-align: right;">Page 542</p> <p>1 them as powder. 2 So that's -- that's the 3 evidence that I look for. Okay. 4 And so are talc-based 5 powders a cause of ovarian cancer? 6 Based upon the epidemiologic 7 studies, I would say no. 8 BY MR. TISI: 9 Q. But you looked at -- okay. 10 Okay. So you asked the question. You 11 looked -- you were looking at whether or 12 not there exists a biologically plausible 13 mechanism, correct? In this section you 14 were looking to see, we observed some 15 increased risk in some studies? 16 A. Yes. 17 Q. And now let's see whether or 18 not there is evidence of a biologically 19 plausible mechanism, why that might be 20 true or not true. 21 A. It's part of the Hill 22 criteria. 23 Q. And you wanted to look at 24 it, right?</p>	<p style="text-align: right;">Page 544</p> <p>1 A. That's correct. 2 Q. May contain -- 3 A. Cornstarch. 4 Q. -- amounts of cornstarch. 5 It may contain asbestos. 6 MR. HUDSON: Objection to 7 form. 8 BY MR. TISI: 9 Q. It may contain silica. It 10 may contain magnesium. It may contain 11 nickel. It may contain a lot of things 12 because it comes from the ground, true? 13 MR. HUDSON: Objection to 14 form. 15 MR. HEGARTY: Objection to 16 form. 17 THE WITNESS: So I -- it may 18 contain. It may not contain. 19 BY MR. TISI: 20 Q. Okay. And so my question -- 21 A. Yes. I just don't know. 22 You need to ask -- 23 Q. So my question is if you're 24 really trying to figure out whether</p>
<p style="text-align: right;">Page 543</p> <p>1 A. That's correct. 2 Q. Okay. And you focused on 3 the question of whether or not pure talc 4 cause -- for the biologic plausibility, 5 you looked at whether or not talc is a 6 carcinogen, correct, talc itself, the 7 talc molecule? 8 A. I looked at the 9 epidemiologic studies -- 10 Q. Epidemiology studies don't 11 have anything to do with what the 12 crystalline structure of talc is, does 13 it? 14 A. That's what the studies were 15 on. 16 Q. The studies were on talcum 17 powder products? 18 A. That's correct. 19 Q. All right. Now, we also 20 know that within -- you said before 21 talcum powder products can contain 22 multiple things. It contains talc. 23 A. Yes. 24 Q. Fragrance?</p>	<p style="text-align: right;">Page 545</p> <p>1 there's a biological mechanism as to 2 whether or not what is in the bottle, 3 causes ovarian cancer, you want to look 4 at the individual constituents in the 5 bottle to see whether or not there's a 6 biologically plausible mechanism for each 7 one of those things, correct? 8 MR. SILVER: Objection to 9 form. 10 MR. HEGARTY: Objection to 11 form. 12 THE WITNESS: That's a 13 hypothetical -- not necessarily. 14 BY MR. TISI: 15 Q. So one of the questions that 16 you might want to ask is, you know, J&amp;J, 17 you know, Imerys, let's see if we can do 18 a survey and see what is actually in the 19 bottle. Tell me what your talcum powder 20 products are made of. 21 That would be a reasonable 22 question to ask, correct? 23 MR. HUDSON: Objection to 24 form.</p>

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<p>1 MR. SILVER: Objection to 2 form. 3 THE WITNESS: I believe 4 that -- I believe J&amp;J does that. 5 BY MR. TISI: 6 Q. Okay. How do you know? Did 7 you ask them? 8 MR. HEGARTY: Objection to 9 form. 10 THE WITNESS: So there are, 11 I mean, there are other sources 12 of -- I rely on the literature. 13 BY MR. TISI: 14 Q. Okay. What literature? 15 Because you -- I'm going to tell you 16 that, I went through your literature. 17 And when you make this statement like you 18 made here, "Since the early '70s, the 19 relevant industries voluntarily 20 eliminated asbestos contamination from 21 talc products." 22 Every time you say that in 23 the medical literature, it is simply a 24 statement with no citation whatsoever.</p>	<p>1 form. 2 MR. SILVER: Objection to 3 form. 4 THE WITNESS: Biological 5 potential mechanism for -- for 6 what? 7 BY MR. TISI: 8 Q. Okay. I'm going to move on. 9 We're running -- 10 MR. TISI: Let's take a 11 quick break. How much time do I 12 have? 13 THE VIDEOGRAPHER: Going off 14 the record 5:54 p.m. 15 (Short break.) 16 THE VIDEOGRAPHER: We are 17 back on the record at 6:13 p.m. 18 BY MR. TISI: 19 Q. Okay. Doctor, we're going 20 to try to wrap up pretty quickly here. 21 So I put in front of you 22 Exhibit Number 30, which is your 23 diaphragm study and Exhibit Number 35, 24 which is a document that I'm going to</p>
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<p>1 And so I want to know what is the medical 2 literature upon which you relied to make 3 that statement, if you know? 4 MR. HEGARTY: Objection to 5 form. 6 THE WITNESS: So there's -- 7 there is the Rohl's reference. 8 There are studies -- 9 BY MR. TISI: 10 Q. That was before 1970. That 11 was the Rohl reference 1976 before. 12 Anything else? 13 A. Okay. So there have been 14 studies, mineralogical studies of 15 contamination in different talc mines in 16 Europe, in Vermont. It's my 17 understanding those studies have shown 18 that talc is asbestos free. 19 Q. And if that was not true, 20 that would -- that would be a potential 21 biologically plausible mechanism, right? 22 MR. HUDSON: Objection to 23 form. 24 MR. HEGARTY: Objection to</p>	<p>1 talk to you about in a minute. 2 (Document marked for 3 identification as Exhibit 4 Muscat-35.) 5 BY MR. TISI: 6 Q. But in your diaphragm study, 7 and we talked before about your 8 hypothesis being identified in -- "The 9 talc cancer hypothesis could be tested 10 with better precision and validity if the 11 exposure to the suspected carcinogen was 12 directly applied to the reproductive 13 tract." 14 Do you remember that? 15 A. Yes. 16 Q. And your meta-analysis was 17 an attempt to do that, with the idea if 18 you use diaphragms, it's a more proximate 19 application of talc to the ovaries? 20 A. That's correct. 21 Q. And you included studies and 22 I remember your premise was to include 23 only studies with talc -- that had talc 24 use, correct?</p>

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<p>1 A. That's correct.</p> <p>2 Q. Not cornstarch?</p> <p>3 A. That's correct.</p> <p>4 Q. So if you look at your</p> <p>5 overview of studies included there,</p> <p>6 there's a chart and numerous studies</p> <p>7 listed.</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And I have done what</p> <p>10 I did before, which is to provide a copy</p> <p>11 of that chart to you as Exhibit Number</p> <p>12 35.</p> <p>13 A. Okay.</p> <p>14 Q. And the studies -- some of</p> <p>15 the studies that you've referred to there</p> <p>16 that I'd like to talk about very briefly.</p> <p>17 A. Okay.</p> <p>18 Q. I'd like to talk about two</p> <p>19 in particular.</p> <p>20 The first one I'd like to</p> <p>21 talk about is Booth 1989.</p> <p>22 A. Okay.</p> <p>23 Q. And the chart that I think</p> <p>24 you draw that from, and you can correct</p>	<p>1 A. I'm sorry?</p> <p>2 Q. We can go off the record if</p> <p>3 you're going to read the article.</p> <p>4 MR. TISI: Unless you're</p> <p>5 going give me some slack on this.</p> <p>6 MR. SILVER: No and no.</p> <p>7 MR. TISI: Well, we're going</p> <p>8 to -- I'm not going to let him</p> <p>9 read the entire article. I would</p> <p>10 assume he would have read his own</p> <p>11 study before walking in there.</p> <p>12 MR. SILVER: He didn't</p> <p>13 choose these question or are in</p> <p>14 the protocol. No one knows.</p> <p>15 MR. HUDSON: It's also not</p> <p>16 his study.</p> <p>17 MR. TISI: It is his study.</p> <p>18 MR. HEGARTY: The Booth</p> <p>19 study?</p> <p>20 MR. TISI: He relied on the</p> <p>21 Booth Study in his -- go ahead.</p> <p>22 MR. HEGARTY: Because you</p> <p>23 are asking him questions about the</p> <p>24 Booth study.</p>
Page 551	Page 553
<p>1 me if I'm wrong is a chart, Table V,</p> <p>2 Roman Numeral V; is that correct?</p> <p>3 A. Yes.</p> <p>4 Q. That's correct?</p> <p>5 A. Yes.</p> <p>6 Q. Can you tell me where in</p> <p>7 that chart you indicate -- that it</p> <p>8 indicates that the powder used to dust</p> <p>9 the diaphragm was talc as opposed to</p> <p>10 cornstarch?</p> <p>11 A. Okay. So it's not in the</p> <p>12 table. It's actually in the methods</p> <p>13 section. Women who reported using a</p> <p>14 contraceptive diaphragm were asked if</p> <p>15 they stored it in talc.</p> <p>16 Q. Okay. And presumably some</p> <p>17 of them did and some of them didn't,</p> <p>18 right?</p> <p>19 A. That's correct.</p> <p>20 Q. Can you tell from the</p> <p>21 Table V which ones -- whether this</p> <p>22 included all women, some of them included</p> <p>23 talc and some that did not? Can you read</p> <p>24 the paper?</p>	<p>1 MR. TISI: I'll ask one more</p> <p>2 time. If you're going to cut me</p> <p>3 off because he's reading a study</p> <p>4 I'm going to ask for more time.</p> <p>5 MR. HEGARTY: Okay. That's</p> <p>6 your choice.</p> <p>7 MR. TISI: Okay. And we'll</p> <p>8 all come back out here.</p> <p>9 MR. HEGARTY: We'll see</p> <p>10 about that, but you're the one who</p> <p>11 presented it to him. He's got an</p> <p>12 opportunity --</p> <p>13 MR. TISI: I agree with you.</p> <p>14 I said he can do it off the record</p> <p>15 if he wants.</p> <p>16 MR. HEGARTY: How much time</p> <p>17 do you need, Dr. Muscat?</p> <p>18 THE WITNESS: I need a few</p> <p>19 minutes because sometimes the</p> <p>20 information is -- could be buried.</p> <p>21 MR. HEGARTY: We can go off</p> <p>22 the record for a few minutes.</p> <p>23 THE WITNESS: Okay.</p> <p>24 THE VIDEOGRAPHER: Going off</p>

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<p style="text-align: right;">Page 554</p> <p>1 the record at 6:19 p.m. 2 (Brief pause.) 3 THE VIDEOGRAPHER: We are 4 back on record at 6:20 p.m. 5 THE WITNESS: So it says 6 right above the discussion 7 section, "There's no significant 8 difference between percentage of 9 cases and controls who had used 10 and kept their diaphragm in talc." 11 BY MR. TISI: 12 Q. Right. But that doesn't 13 refer to the -- you don't know how many 14 of them used -- dusted with talc and how 15 many used -- dusted with cornstarch? 16 This appears, Table V appears to be 17 diaphragm studied with both talc and 18 cornstarch, right? It's the combined 19 result? 20 A. Yes, that's correct. That's 21 correct. 22 Q. So you don't know -- so you 23 don't know from -- you don't know from 24 the study. Some of these patients would</p>	<p style="text-align: right;">Page 556</p> <p>1 A. It must have been 2 calculated. 3 Q. And then the Harlow and 4 Weiss study, 1989, which I believe is Tab 5 3, the data -- it's Tab 1. The data is 6 pulled from the chart in Table 1, right? 7 Adjusted odds ratio of .5. You see .5 8 towards diaphragm storage only, and with 9 other methods, .5. That is where that 10 was pulled from, right? 11 MR. HUDSON: I think you 12 need to clarify which study. 13 MR. TISI: It's Harlow and 14 Weiss. Not Harlow. Harlow and 15 Weiss. 16 THE WITNESS: Oh, okay. 17 BY MR. TISI: 18 Q. Go to Table 1. 19 A. Okay. 20 Q. That's where you got that 21 data from, right? 22 A. It was derived from Table 1. 23 Q. Okay. Do you agree that the 24 Table 1 heading, "Perineal Use of</p>
<p style="text-align: right;">Page 555</p> <p>1 have used talc and some would have used 2 cornstarch, correct, in Table V? 3 MR. HEGARTY: Objection to 4 form. 5 THE WITNESS: You can 6 calculate the talc-specific 7 diaphragm used based upon these 8 numbers in the table -- in the 9 discussion. 10 BY MR. TISI: 11 Q. Did you? 12 A. I think that's what was 13 done. 14 Q. You sure? 15 A. I can't be 100 percent sure 16 because Dr. Huncharek is the lead author. 17 But that, I'm pretty confident that's 18 probably what he did because you can go 19 ahead -- once you have the percentages of 20 the cases and controls who have used talc 21 diaphragm, you can calculate the odds 22 ratio. 23 Q. Where did the point -- where 24 did you get the .75 from?</p>	<p style="text-align: right;">Page 557</p> <p>1 Talc-Containing Powder and Cornstarch"? 2 A. Yeah, that's correct. 3 Q. These women used both talc 4 and cornstarch. This wasn't pure talc, 5 was it? 6 MR. SILVER: Objection to 7 form. 8 THE WITNESS: I think there 9 was a separate question on 10 cornstarch. 11 BY MR. TISI: 12 Q. It was not in this chart, is 13 it? In fact, the odds ratio that you use 14 is exactly "diaphragm storage only and 15 with other methods"? 16 MR. HUDSON: Objection to 17 form. 18 BY MR. TISI: 19 Q. Do you see that? .5 with a 20 relative risk -- I'm sorry with a 21 confidence interval of .2 to 1.3: It's 22 exactly what was reported in your chart 23 on Table 1, right? 24 A. Okay.</p>

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<p style="text-align: right;">Page 558</p> <p>1 Q. The study shouldn't have 2 been included in this, should it, because 3 some women used cornstarch, right? 4 MR. SILVER: Objection to 5 form. 6 MR. HUDSON: Objection to 7 form. 8 THE WITNESS: So can I have 9 a minute to go back and look at 10 this? 11 MR. TISI: We can go off the 12 record. You can take as much time 13 as you want. 14 THE WITNESS: Okay. 15 THE VIDEOGRAPHER: Off the 16 record. 6:24 p.m. 17 (Brief pause.) 18 THE VIDEOGRAPHER: Back on 19 record. 6:28 p.m. 20 BY MR. TISI: 21 Q. Can you tell me why Booth 22 was included? 23 A. I'm sorry. What was that? 24 Q. Tell me why Booth was</p>	<p style="text-align: right;">Page 560</p> <p>1 vast majority of the powder was talc. 2 But yeah, I agree it's -- that is 3 probably something that was not 4 specified. 5 Q. Okay. And you probably 6 shouldn't have included it for that 7 reason? 8 MR. HEGARTY: Objection to 9 form. 10 MR. SILVER: Objection to 11 form. 12 THE WITNESS: No. No, I 13 wouldn't say I wouldn't have 14 included it. But I think it 15 should be clarified as to regard 16 the exposure classification. 17 BY MR. TISI: 18 Q. One other question, and I'm 19 going to go to the last, and I'm going to 20 mark this as a -- we talked before about 21 the consistency between different study 22 designs. 23 Do you remember we talked 24 about the 1.9 with a relative risk of .99</p>
<p style="text-align: right;">Page 559</p> <p>1 included in the -- because the statistic 2 you used was derived from a chart that 3 had both talc and cornstarch exposure, 4 right? 5 MR. HEGARTY: Objection to 6 form. 7 MR. HUDSON: Objection to 8 form. 9 THE WITNESS: We're talking 10 about -- 11 BY MR. TISI: 12 Q. Table 1? 13 A. -- Booth or Harlow? 14 Q. Harlow. I'm sorry. I meant 15 to say Harlow. Harlow and Weiss. 16 A. So I think that's the case, 17 yes. 18 Q. Okay. And so you think 19 that -- do you think that study should 20 not have been included in your study? 21 A. I think there was an 22 assumption here that based upon the -- 23 the use of cornstarch was very low in 24 cases and controls in the study, that the</p>	<p style="text-align: right;">Page 561</p> <p>1 to -- I think it was 1.6 seen in the 2 hospital studies versus the population 3 studies. 4 Do you remember we talked 5 about that? 6 A. Yes. 7 Q. And the only reason that 8 they were not consistent in your view was 9 because the confidence interval closed 10 went over 1 to 1 -- or 2.99 correct? 11 MR. HEGARTY: Objection to 12 form. 13 THE WITNESS: So I'm sorry, 14 the consistency of the studies is 15 the -- 16 BY MR. TISI: 17 Q. Is -- you felt that this was 18 an inconsistency between the 19 hospital-based studies and the 20 population-based studies, correct? 21 A. They yielded some different 22 relative risks. 23 Q. Right. But they were both 24 in the recollection of the -- the point</p>

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<p style="text-align: right;">Page 562</p> <p>1 estimate was both positive for cause, 2 correct -- positive for an association? 3 MR. HEGARTY: Objection to 4 form. 5 THE WITNESS: So they 6 were -- I don't have the exact 7 numbers. But they were above 1.0. 8 BY MR. TISI: 9 Q. Now, the uncontrolled 10 confounding, which is the last one I'm 11 going to talk about that really briefly. 12 One of the issues that you 13 raised was -- on Page 23 of the report to 14 the FDA. You said, Smokers are more 15 likely to engage in perineal talc dusting 16 compared to nonsmokers; therefore, an 17 imbalance of smokers across case-control 18 in the epi studies" -- "epidemiologic 19 studies could contribute to a spurious 20 positive association?" 21 A. I'm sorry. Where is this? 22 Q. It's in your Citizen's 23 Petition, Page 23. Number 25. Page 23 24 of Exhibit 25. I have it up on the</p>	<p style="text-align: right;">Page 564</p> <p>1 BY MR. TISI: 2 Q. You know Meta-Analysis 3 Research Group did? 4 MR. HEGARTY: Objection to 5 form. 6 THE WITNESS: I don't 7 recall. But -- 8 BY MR. TISI: 9 Q. That sounds right, right? 10 MR. HEGARTY: Objection to 11 form. 12 THE WITNESS: I've never 13 actually seen it. Okay. But a 14 proposal on smoking was done, 15 okay. 16 BY MR. TISI: 17 Q. Let me ask you this. Do you 18 know whether or not the company has taken 19 the position that smoking is not a 20 confounder for ovarian cancer? 21 MR. HUDSON: Objection to 22 form. 23 THE WITNESS: I don't know 24 that.</p>
<p style="text-align: right;">Page 563</p> <p>1 screen. The last sentence -- 2 A. Okay, thanks. Okay. 3 Q. It's the last sentence -- 4 A. Sorry. 5 Q. -- of the second paragraph. 6 You talk about smoking. 7 Do you see that? 8 A. Yes. 9 Q. Okay. You raise the 10 possibility that perhaps smoking could 11 account for, since there was an imbalance 12 that you suggested between people who use 13 talc and not use talc, that maybe that 14 would have confounded the results? 15 A. I see that. 16 Q. Okay. I'm going to make 17 three points, and I'm going to be done. 18 A. Okay. 19 Q. Let me ask you Number 1. 20 You proposed a smoking study to the 21 company, and they didn't do it, correct? 22 MR. HEGARTY: Objection to 23 form. 24 THE WITNESS: No, I didn't.</p>	<p style="text-align: right;">Page 565</p> <p>1 BY MR. TISI: 2 Q. I'm going to show you again 3 from Dr. Nicholson who spoke for the 4 company on this issue? 5 A. Okay. 6 Q. And see if you agree with 7 her. 8 MR. TISI: Would you please 9 play Clip 2. 10 (Video playback.) 11 -- this particular proposal. 12 Looking at -- did you ever 13 contact" -- 14 (Stop video playback.) 15 MR. TISI: That's not it. 16 Can we go off the record for 17 one minute. I'm having a 18 technical issue. 19 THE VIDEOGRAPHER: Going off 20 the record 6:33 p.m. 21 (Brief pause.) 22 THE VIDEOGRAPHER: We are 23 back on record at 6:37 p.m. 24 (Video playback.)</p>

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<p>1 MS. NICHOLSON: Care</p> <p>2 providers have to be very heavily</p> <p>3 adjudicated and documented.</p> <p>4 There's no way this is the</p> <p>5 official record of any --</p> <p>6 (Video playback paused.)</p> <p>7 MR. TISI: No, no. Keep</p> <p>8 going.</p> <p>9 (Video playback.)</p> <p>10 MR. TISI: I'm going to show</p> <p>11 you more evidence of this, but</p> <p>12 let's just -- let's just move on</p> <p>13 here.</p> <p>14 Putting aside this</p> <p>15 particular proposal. Looking</p> <p>16 at -- did you ever contact or see</p> <p>17 any evidence that an</p> <p>18 epidemiologist within the company</p> <p>19 ever was contacted to see if you</p> <p>20 can control for smoking?</p> <p>21 MS. NICHOLSON: No.</p> <p>22 MR. TISI: And if your</p> <p>23 lawyers march into court and</p> <p>24 suggest, well, a particular</p>	<p>1 A. So, yeah, let me just</p> <p>2 explain this. I know Dr. Huncharek had</p> <p>3 written that, and these are one of the</p> <p>4 areas where I was less agreeable in terms</p> <p>5 of my thinking. The reason that's in</p> <p>6 there is because smoking is a risk factor</p> <p>7 for the mucinous form. Okay. So I know</p> <p>8 he's very interested in that.</p> <p>9 I think because it's a</p> <p>10 minority of ovarian cancers, that if you</p> <p>11 did not adjust for the effect of smoking,</p> <p>12 it may not have a big impact on kind of</p> <p>13 the overall relative risk.</p> <p>14 Q. Okay. So anyone who would</p> <p>15 come in and suggest that there was</p> <p>16 uncontrolled confounding due to smoking,</p> <p>17 in your view that was -- that was not an</p> <p>18 explanation for what was seen in the</p> <p>19 studies?</p> <p>20 A. I would -- I'd be more</p> <p>21 specific and say that is a -- probably</p> <p>22 cause a concern for the mucinous form of</p> <p>23 ovarian cancer.</p> <p>24 Q. And most of the ovarian</p>
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<p>1 plaintiff had smoking, it was a</p> <p>2 potential confounder, they</p> <p>3 wouldn't know that because you</p> <p>4 guys didn't really study it,</p> <p>5 right?</p> <p>6 DEFENSE COUNSEL: Objection.</p> <p>7 MS. NICHOLSON: I would</p> <p>8 agree, and I wouldn't support</p> <p>9 anyone saying that smoking is a</p> <p>10 confounder who didn't adjust for</p> <p>11 it.</p> <p>12 MR. TISI: Thank you.</p> <p>13 (Video playback ended.)</p> <p>14 BY MR. TISI:</p> <p>15 Q. Let me ask you this. Do you</p> <p>16 agree with the company that smoking would</p> <p>17 not be a confounder for these studies</p> <p>18 that you looked at?</p> <p>19 MR. HEGARTY: Objection.</p> <p>20 BY MR. TISI:</p> <p>21 Q. Do you agree with</p> <p>22 Dr. Nicholson?</p> <p>23 A. So I think so.</p> <p>24 Q. Okay.</p>	<p>1 cancers that were looked at were of the</p> <p>2 serous form, correct?</p> <p>3 MR. HEGARTY: Objection to</p> <p>4 form.</p> <p>5 THE WITNESS: Well, I'm not</p> <p>6 sure most of these studies</p> <p>7 specified. But he just assumed</p> <p>8 the percentages most of them would</p> <p>9 be serous.</p> <p>10 MR. HUDSON: Counsel, I</p> <p>11 understand that we have reached</p> <p>12 the seven-hour mark.</p> <p>13 MR. TISI: Yeah, no, I</p> <p>14 appreciate that. And, Doctor, I</p> <p>15 appreciate your time. And we</p> <p>16 reserve the right to follow up on</p> <p>17 some things. But we're done for</p> <p>18 tonight according to your counsel.</p> <p>19 THE VIDEOGRAPHER: Going off</p> <p>20 the record at 6:40 p.m.</p> <p>21 (Brief pause.)</p> <p>22 THE VIDEOGRAPHER: Back on</p> <p>23 record 6:45 p.m.</p> <p>24 - - -</p>



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<p style="text-align: right;">Page 570</p> <p>1 EXAMINATION</p> <p>2 - - -</p> <p>3 BY MR. HEGARTY:</p> <p>4 Q. Good afternoon, Dr. Muscat.</p> <p>5 A. It's been a long afternoon.</p> <p>6 Q. Yeah, we're almost in the</p> <p>7 evening. I promise to keep this very</p> <p>8 short. I'm not sure if we had the chance</p> <p>9 today to learn your full name. Would you</p> <p>10 please tell us your full name.</p> <p>11 A. It's Joshua Muscat.</p> <p>12 Q. And I want to spend just a</p> <p>13 few moments discussing your background</p> <p>14 and experience. First of all, can you</p> <p>15 give us a very brief summary of your</p> <p>16 educational background?</p> <p>17 A. Okay. Received my MPH from</p> <p>18 Yale University and Ph.D. in</p> <p>19 environmental health sciences.</p> <p>20 Q. What is an MPH by the way?</p> <p>21 A. I'm sorry. Master's of</p> <p>22 public health.</p> <p>23 Q. You mentioned that you do</p> <p>24 have a doctorate degree?</p>	<p style="text-align: right;">Page 572</p> <p>1 to medical students?</p> <p>2 A. Yes, I have.</p> <p>3 Q. Is that an area that you</p> <p>4 still are involved in teaching?</p> <p>5 A. Yes. As a matter of fact, I</p> <p>6 should be teaching right now, so --</p> <p>7 Q. What class are you missing</p> <p>8 right now?</p> <p>9 A. There's a substitute, right.</p> <p>10 Actually it's cancer epidemiology.</p> <p>11 Q. And who is in the class</p> <p>12 tonight?</p> <p>13 MR. TISI: Objection.</p> <p>14 THE WITNESS: There are five</p> <p>15 graduate students.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. Graduate students in what</p> <p>18 discipline?</p> <p>19 A. In epidemiology.</p> <p>20 Q. Where do you work? In other</p> <p>21 words, where is the Penn State campus</p> <p>22 that you work?</p> <p>23 A. Okay. So I'm located in the</p> <p>24 College of Medicine and that is my</p>
<p style="text-align: right;">Page 571</p> <p>1 A. That's correct.</p> <p>2 Q. And what is the nature of</p> <p>3 this doctorate degree?</p> <p>4 A. Some environmental health</p> <p>5 science is my track. Within that degree</p> <p>6 was in environmental epidemiology.</p> <p>7 Q. Since getting your Ph.D.,</p> <p>8 your doctorate, have you also had a</p> <p>9 particular focus in the area of cancer</p> <p>10 epidemiology?</p> <p>11 A. That's correct.</p> <p>12 Q. Can you tell us where you</p> <p>13 work?</p> <p>14 A. So I work at, since 2004,</p> <p>15 Penn State College of Medicine,</p> <p>16 department of public health sciences.</p> <p>17 Q. And what is your current</p> <p>18 title at Penn State?</p> <p>19 A. Professor.</p> <p>20 Q. Have you taught courses over</p> <p>21 the years at Penn State on cancer</p> <p>22 epidemiology?</p> <p>23 A. Yes, I have.</p> <p>24 Q. Have you taught such courses</p>	<p style="text-align: right;">Page 573</p> <p>1 department, department of public health</p> <p>2 sciences within College of Medicine at</p> <p>3 Hershey, Pennsylvania.</p> <p>4 Q. How long have you taught at</p> <p>5 Penn State?</p> <p>6 A. 14 years.</p> <p>7 Q. In addition to teaching</p> <p>8 cancer epidemiology, do you also do</p> <p>9 research in cancer epidemiology at Penn</p> <p>10 State?</p> <p>11 A. Yes, I do.</p> <p>12 Q. We talked about a couple of</p> <p>13 your publications today. But you have a</p> <p>14 number of publications we haven't talked</p> <p>15 about. I believe in looking at your CV,</p> <p>16 it looked like you have been involved in</p> <p>17 seven book chapters and some 185</p> <p>18 articles. Does that sound right?</p> <p>19 A. That's correct.</p> <p>20 Q. And have any of those book</p> <p>21 chapters or articles dealt with cancer</p> <p>22 epidemiology?</p> <p>23 A. Most of them.</p> <p>24 Q. And have some, as we've</p>



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<p style="text-align: right;">Page 574</p> <p>1 talked about today, dealt with talc and 2 ovarian cancer? 3 A. That's correct. 4 Q. Have you also served as a 5 reviewer of medical and scientific 6 literature for publications? 7 A. Yes. 8 Q. Is this part of what we've 9 been talking about today of the peer 10 review process? 11 A. That's correct. 12 Q. In other words, are you -- 13 have you been and are you a peer reviewer 14 for authors who want their papers 15 published in the scientific literature? 16 A. Yes. 17 Q. Now, you have been asked 18 over the course of today by lawyers for 19 plaintiffs -- is it your understanding in 20 this litigation that they claim that you 21 either hid funding sources or otherwise 22 failed to make proper disclosures of 23 conflicts in the papers that you've 24 written.</p>	<p style="text-align: right;">Page 576</p> <p>1 conclusion? 2 MR. TISI: Objection. 3 THE WITNESS: Yes. 4 MR. TISI: Form. 5 BY MR. HEGARTY: 6 Q. We talked briefly, or in 7 some respect about the diaphragm study 8 published in 2007. Can you tell us what 9 journal that was published in? 10 A. That was the European 11 Journal of Cancer Prevention. 12 Q. Did that article go through 13 peer review? 14 A. Yes, it did. 15 Q. We talked a little bit about 16 some of the data. But generally have you 17 been shown anything here over the course 18 of today that establishes that any of the 19 data reported was inaccurate? 20 MR. TISI: Objection. 21 THE WITNESS: No. 22 BY MR. HEGARTY: 23 Q. Are you aware of anyone in 24 the scientific community identifying any</p>
<p style="text-align: right;">Page 575</p> <p>1 Is any of that true 2 Dr. Muscat? 3 MR. TISI: Objection. 4 THE WITNESS: No, it's not 5 true. 6 BY MR. HEGARTY: 7 Q. You were asked about whether 8 you are aware of any funding Imerys or 9 J&amp;J provided for the white papers that 10 were prepared as part of the work for 11 Crowell &amp; Moring back in 2005. Do you 12 recall those questions? 13 A. Yes. 14 Q. And if you had been made 15 aware of the funding sources back at that 16 time, would it have made any difference 17 in the work you did on the two white 18 papers? 19 A. No. 20 Q. In other words, would you 21 still have approached the work as an 22 independent scientist where your analysis 23 and results would be based solely on the 24 data and not reaching any particular</p>	<p style="text-align: right;">Page 577</p> <p>1 inaccuracies in the data or the 2 conclusions? 3 MR. TISI: Objection. 4 THE WITNESS: Not that I'm 5 aware of. 6 BY MR. HEGARTY: 7 Q. And does the data in the 8 diaphragm study that looks at talc-dusted 9 diaphragms and ovarian cancer, does that 10 data show no causal connection between 11 the use of talc-dusted diaphragms and 12 ovarian cancer? 13 MR. TISI: Objection. 14 THE WITNESS: That's 15 correct. 16 BY MR. HEGARTY: 17 Q. And have there been other 18 studies reporting no causal link between 19 the use of talc-dusted diaphragms and 20 ovarian cancer? 21 MR. TISI: Objection. 22 BY MR. HEGARTY: 23 Q. That you can recall? 24 A. Other studies?</p>

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<p style="text-align: right;">Page 578</p> <p>1 Q. If you know. If you recall 2 other studies reporting on talc-dusted 3 diaphragms and ovarian cancer. 4 MR. TISI: Objection. 5 THE WITNESS: I think there 6 may have been some reports in some 7 of the cohort studies that were 8 not included in that. I can't 9 recall the specifics. 10 BY MR. HEGARTY: 11 Q. Is it your understanding 12 that the results reported in your 13 diaphragm study are consistent with what 14 other studies have reported? 15 A. Yes. 16 Q. We looked at the disclosure 17 that you provided for the 2007 diaphragm 18 study. Do you recall doing that? 19 A. Yes. 20 Q. To your knowledge, did J&amp;J 21 suggest any revisions to the diaphragm 22 paper? 23 A. Not to my knowledge. 24 Q. Did J&amp;J request or require</p>	<p style="text-align: right;">Page 580</p> <p>1 Q. And to your knowledge did 2 J&amp;J have any involvement whatsoever in 3 preparation of the published article, the 4 2008 published article? 5 A. They did not. 6 Q. Have you seen anywhere that 7 J&amp;J suggested any changes to that 8 article? 9 A. No. 10 MR. TISI: Objection. 11 BY MR. HEGARTY: 12 Q. Or requested or required any 13 changes? 14 MR. TISI: Objection. 15 THE WITNESS: No. 16 BY MR. HEGARTY: 17 Q. Did you have any 18 communication at all with J&amp;J about 19 preparation of The Critical Review, 20 either white paper or the paper that 21 ultimately was published in the European 22 Journal of Cancer Prevention? 23 A. No. 24 Q. You told us about this</p>
<p style="text-align: right;">Page 579</p> <p>1 any changes be made? 2 A. Not to my knowledge. 3 Q. Did you have any 4 communications at all with J&amp;J about the 5 diaphragm white paper or the diaphragm 6 published study? 7 A. No. 8 Q. From your standpoint did J&amp;J 9 have any involvement in the results or 10 final wording of the published article on 11 talc-dusted diaphragms? 12 A. No. 13 MR. TISI: Objection. 14 BY MR. HEGARTY: 15 Q. Now, with regard to the new 16 critical review white paper, who wrote 17 that paper, the 2008 paper? 18 A. The published paper? 19 Q. Yes. 20 A. That was me. 21 Q. And was that a paper looking 22 at the science on talc and ovarian 23 cancer? 24 A. Yes.</p>	<p style="text-align: right;">Page 581</p> <p>1 earlier, but over the course of writing 2 the new critical review paper, did you 3 perceive that the earlier work with 4 Crowell &amp; Moring had ended and you were 5 now working on a separate project? 6 A. Correct. 7 Q. Did J&amp;J have any involvement 8 in the writing of this new critical 9 review paper? 10 MR. TISI: Objection. 11 THE WITNESS: No. 12 BY MR. HEGARTY: 13 Q. Did you have any 14 communication with J&amp;J about writing this 15 new critical review paper? 16 A. No. 17 Q. Did J&amp;J comment on or 18 suggest any revision -- 19 MR. TISI: Objection. 20 BY MR. HEGARTY: 21 Q. -- to this critical review 22 paper? 23 A. No. 24 Q. Now, did you ultimately</p>



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<p>1 submit the new critical review paper for 2 publishing in the European Journal of 3 Cancer Prevention? 4 A. That's correct. 5 Q. Was J&amp;J involved at all in 6 submitting this new critical review 7 paper? 8 A. No. 9 Q. Did you give J&amp;J a copy of 10 the new critical review paper that you 11 were submitting? 12 A. No. 13 Q. You told us earlier that you 14 did make a reference in the disclosure 15 part of the new critical review paper to 16 Crowell &amp; Moring. And why did you 17 include that, the reference to Crowell &amp; 18 Moring? 19 A. For transparency purposes. 20 Q. Did the funds from Crowell &amp; 21 Moring that came from J&amp;J and Imerys that 22 went to the white paper, The Critical 23 Review white paper, fund the work on this 24 new published study?</p>	<p>1 MR. TISI: Objection. 2 BY MR. HEGARTY: 3 Q. Dr. Muscat, from your 4 standpoint would it be fair for anyone to 5 claim that J&amp;J is somehow at fault for 6 you not including the reference to the 7 company in that disclosure? 8 MR. TISI: Objection. 9 THE WITNESS: I'm sorry. 10 What was that? 11 BY MR. HEGARTY: 12 Q. From your standpoint, would 13 it be fair for anyone to claim that J&amp;J 14 is somehow at fault for you not including 15 the reference -- 16 A. No. 17 Q. -- to the company in your 18 disclosure? 19 A. No. 20 Q. Have you seen anything -- 21 MR. TISI: Objection. 22 BY MR. HEGARTY: 23 Q. -- that shows that J&amp;J was 24 the reason that you were not made aware</p>
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<p>1 A. No. 2 Q. Where did the funds come 3 from that reimbursed you for your time 4 for this new critical review paper that 5 was published in 2008? 6 A. That came from NCI grant 7 that was awarded to me. 8 Q. Did you disclose that 9 funding source in the 2008 paper? 10 A. Yes, I did. 11 Q. And did you consider the 12 disclosure at the time to be true, 13 accurate and proper in all respects? 14 A. Yes. 15 Q. Is that still the case? 16 A. Yes. 17 Q. Now, given that, as you've 18 told us, The Critical Review paper was 19 essentially a new work. If you had been 20 made aware of the original funding for 21 the white paper for Crowell &amp; Moring, 22 would you still have kept the disclosure 23 essentially the same as it is now? 24 A. Yes.</p>	<p>1 of the funding for the white paper in the 2 first place? 3 MR. TISI: Objection. 4 THE WITNESS: No. 5 BY MR. HEGARTY: 6 Q. Have you seen anything 7 showing that J&amp;J even knew you were 8 publishing the new critical review paper? 9 A. No. 10 Q. Or that J&amp;J knew that you 11 were including in the disclosure Crowell 12 &amp; Moring and the other grant that you 13 included? 14 MR. TISI: Objection. 15 THE WITNESS: That's 16 correct. 17 BY MR. HEGARTY: 18 Q. Did J&amp;J have any involvement 19 whatsoever in the disclosure that you 20 made for the new critical review paper? 21 A. No. 22 Q. So would it be proper to 23 argue that the new critical review 24 article was written by you for J&amp;J to</p>



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<p style="text-align: right;">Page 586</p> <p>1 somehow influence scientists or 2 regulators to find talc safe? 3 MR. TISI: Objection. 4 THE WITNESS: No. 5 BY MR. HEGARTY: 6 Q. Was that what you were doing 7 by this article? 8 MR. TISI: Objection. 9 THE WITNESS: No. 10 BY MR. HEGARTY: 11 Q. Are you aware of anyone in 12 the scientific community identifying any 13 inaccuracies in the data in the article 14 or the conclusions? 15 A. No. 16 Q. Have there been any other 17 studies reporting similar conclusions 18 that the data shows that talcum powder 19 use does not cause ovarian cancer? 20 MR. TISI: Objection. 21 Beyond the scope. 22 THE WITNESS: I'm sorry, can 23 you repeat that? 24 BY MR. HEGARTY:</p>	<p style="text-align: right;">Page 588</p> <p>1 Q. Were three of the authors on 2 the working group at IARC that you -- 3 where you attended as an observer? 4 A. That's correct. 5 Q. And that's Jack Siemietycki, 6 Sue Hankinson, and Elizabeth Weiderpass. 7 So whoever wrote this is 8 essentially the IARC working group, 9 correct? 10 MR. TISI: Objection. 11 THE WITNESS: That's 12 correct. 13 BY MR. HEGARTY: 14 Q. You were asked questions 15 over the course of the day about 16 dose-response. If you turn second page 17 of this study, left-hand column, 18 bottom -- end of the second paragraph. 19 You see where the line begins, "The main 20 epidemiologic evidence"? 21 A. Oh, okay. Yes. Thank you. 22 Yes. 23 Q. Would you read that for me? 24 A. Okay. "The main</p>
<p style="text-align: right;">Page 587</p> <p>1 Q. Sure. Have there been other 2 studies reporting similar conclusions 3 that the data shows that talcum powder 4 use does not cause ovarian cancer? 5 A. Yes. 6 MR. TISI: Objection to 7 form. 8 MR. HEGARTY: What exhibit 9 number are we on? 36? 10 (Document marked for 11 identification as Exhibit 12 Muscat-36.) 13 BY MR. HEGARTY: 14 Q. Very quickly, Doctor, I'm 15 going to mark as Exhibit 36 a copy of a 16 2008 publication, first author Langseth, 17 called "Perineal Use of Talc and Risk of 18 Ovarian Cancer." 19 Are you familiar with this 20 article? 21 A. Yes. 22 Q. Was this published the same 23 year as your 2008 review paper? 24 A. Yes.</p>	<p style="text-align: right;">Page 589</p> <p>1 epidemiologic evidence against the 2 association is the absence of clear 3 exposure-response associations in most 4 studies, as well as the absence of 5 overall excess risk in the cohort study." 6 Q. And these are the IARC 7 working group authors who are saying 8 this, that they're -- that the main 9 epidemiological evidence against the 10 association is the absence of a clear 11 exposure response, and that means the 12 absence of dose-response, correct? 13 MR. TISI: Objection. 14 THE WITNESS: That's 15 correct. 16 BY MR. HEGARTY: 17 Q. And if you look over -- and 18 backing up. Is that essentially the same 19 thing that you -- the conclusions that 20 you came to in your 2008 paper? 21 A. That's correct. 22 Q. Still stay with that paper. 23 A. Sorry. 24 Q. Look over the right-hand</p>

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<p style="text-align: right;">Page 590</p> <p>1 column under "Proposal to Research 2 community." 3 A. Yes. 4 Q. Would you read for me the 5 first sentence under that section? 6 A. Okay. Okay. 7 "The current body of 8 experimental and epidemiological evidence 9 is insufficient to establish a causal 10 association between" -- I'm sorry. 11 Excuse me -- "between perineal use of 12 talc and ovarian cancer risk." 13 Q. And is that essentially the 14 same conclusion that you came to in your 15 2008 critical review paper? 16 A. Yes, it is. 17 Q. Again, are these the IARC 18 working group members who came to the 19 same conclusion? 20 A. That's correct. 21 Q. Okay. You can put that 22 aside. You were asked a little bit about 23 making comments to papers, to the extent 24 that anybody made comments to you, did</p>	<p style="text-align: right;">Page 592</p> <p>1 disclosure? 2 MR. TISI: Objection. 3 THE WITNESS: No. 4 BY MR. HEGARTY: 5 Q. Or knew what you were 6 disclosing in your IARC disclosure? 7 A. No. 8 Q. If you had been made aware 9 of any involvement in J&amp;J, would it have 10 been made any difference in your work 11 that you did as an observer at IARC? 12 MR. TISI: Objection. 13 THE WITNESS: No. 14 BY MR. HEGARTY: 15 Q. In other words, would you 16 still approach being an observer as an 17 independent scientist where your 18 contribution would be based solely on the 19 data? 20 A. That's correct. 21 MR. TISI: Objection. 22 BY MR. HEGARTY: 23 Q. You were asked a number of 24 questions about the work that you did to</p>
<p style="text-align: right;">Page 591</p> <p>1 such comments change the substance of the 2 data that you used to report on or come 3 to the conclusions about -- 4 A. No. 5 MR. TISI: Objection. 6 BY MR. HEGARTY: 7 Q. Would you ever allow a third 8 party to change the data, results, or 9 conclusions from one of your studies? 10 MR. TISI: Objection. 11 THE WITNESS: No. 12 BY MR. HEGARTY: 13 Q. Did that happen here, what 14 we talked about here today, or ever in 15 your career? 16 A. No, it did not. 17 MR. TISI: Objection. 18 THE WITNESS: Never. 19 BY MR. HEGARTY: 20 Q. You were also asked about 21 your disclosure to IARC. Have you seen 22 any documentation showing that J&amp;J was in 23 any way asked -- that J&amp;J in any way 24 asked that it not be identified in your</p>	<p style="text-align: right;">Page 593</p> <p>1 prepare a paper that was submitted to FDA 2 in response to the Citizen's Petition. 3 Do you recall -- 4 A. Yes. 5 Q. Do you recall a number of 6 questions on that subject area? 7 A. Yes. 8 Q. And again, what was the 9 extent of your involvement in that 10 submission? Would you tell us again? 11 A. The extent of my 12 contribution to that paper? 13 Q. Well, let me skip over that 14 because of time. Let me jump to 15 something else. 16 A. Okay. 17 Q. You were asked about that 18 paper -- that paper responding to the 19 Citizen's Petition. You were asked about 20 your 2011 paper and other papers 21 referring to the 2003 Huncharek 22 meta-analysis. 23 Do you recall those 24 questions?</p>



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<p style="text-align: right;">Page 594</p> <p>1 A. Yes.</p> <p>2 Q. First of all, do you recall</p> <p>3 that in the -- the paper that was</p> <p>4 submitted by you and Dr. Huncharek to FDA</p> <p>5 included some 23 different pieces of</p> <p>6 scientific literature?</p> <p>7 A. Was that the number of</p> <p>8 references.</p> <p>9 Q. Yes.</p> <p>10 A. Yes. Okay.</p> <p>11 Q. And also in Huncharek 2003</p> <p>12 paper there were some 15 or 20-odd</p> <p>13 references in that paper as well?</p> <p>14 MR. TISI: Objection.</p> <p>15 THE WITNESS: Yes.</p> <p>16 BY MR. HEGARTY:</p> <p>17 Q. And all those references</p> <p>18 were in the scientific and medical</p> <p>19 literature available for anyone to go</p> <p>20 online and pull the papers down</p> <p>21 themselves?</p> <p>22 MR. TISI: Objection.</p> <p>23 THE WITNESS: Yes.</p> <p>24 BY MR. HEGARTY:</p>	<p style="text-align: right;">Page 596</p> <p>1 A. Yes.</p> <p>2 Q. And were the results and</p> <p>3 conclusions proper?</p> <p>4 A. Yes. I believe so.</p> <p>5 Q. And, Dr. Muscat, you have</p> <p>6 reviewed the science, the medical and</p> <p>7 scientific literature on talc and ovarian</p> <p>8 cancer; is that correct?</p> <p>9 A. Yes.</p> <p>10 Q. And you would consider</p> <p>11 yourself an expert in the area of talcum</p> <p>12 powder use and ovarian cancer, correct?</p> <p>13 MR. TISI: Objection.</p> <p>14 THE WITNESS: Yes.</p> <p>15 MR. TISI: Objection.</p> <p>16 Outside the scope.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. Do you agree that the</p> <p>19 science shows that Johnson &amp; Johnson</p> <p>20 talcum powder products do not cause</p> <p>21 ovarian cancer?</p> <p>22 MR. TISI: Objection.</p> <p>23 THE WITNESS: Yes.</p> <p>24 BY MR. HEGARTY:</p>
<p style="text-align: right;">Page 595</p> <p>1 Q. You were also asked about,</p> <p>2 whether anyone commented on the substance</p> <p>3 of the submission to FDA. Did any</p> <p>4 comments, to your knowledge, change any</p> <p>5 of the substance of the paper?</p> <p>6 A. Not that I'm aware of.</p> <p>7 Q. Change the results or</p> <p>8 conclusions?</p> <p>9 A. Not that I'm aware of.</p> <p>10 Q. Again, would you ever allow</p> <p>11 a third party to change the data,</p> <p>12 results, or conclusions in a paper like</p> <p>13 that?</p> <p>14 A. No.</p> <p>15 Q. And you have reviewed the</p> <p>16 submission to FDA, correct?</p> <p>17 A. Yes.</p> <p>18 Q. Is the data accurately set</p> <p>19 out?</p> <p>20 MR. TISI: Objection.</p> <p>21 THE WITNESS: I think so.</p> <p>22 BY MR. HEGARTY:</p> <p>23 Q. Was it an independent review</p> <p>24 of the relevant data?</p>	<p style="text-align: right;">Page 597</p> <p>1 Q. Is the best evidence for</p> <p>2 this the series of large prospective</p> <p>3 cohort studies of talcum powder users?</p> <p>4 MR. TISI: Objection.</p> <p>5 THE WITNESS: So yes.</p> <p>6 MR. TISI: Outside the</p> <p>7 scope.</p> <p>8 BY MR. HEGARTY:</p> <p>9 Q. And do these studies taken</p> <p>10 together show that the use of talcum</p> <p>11 powder products do not cause ovarian</p> <p>12 cancer?</p> <p>13 MR. TISI: Objection.</p> <p>14 Outside the scope.</p> <p>15 THE WITNESS: That's</p> <p>16 correct.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. And do these studies</p> <p>19 evaluate talcum powder and whatever else</p> <p>20 is in the powder, including asbestos as</p> <p>21 alleged by the plaintiffs in this case?</p> <p>22 A. That's correct.</p> <p>23 Q. And so even if, as</p> <p>24 plaintiffs alleged, talcum powder</p>

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<p style="text-align: right;">Page 598</p> <p>1 products that were studied that were used  2 had asbestos or anything else in it, do  3 those studies still show no causal link  4 between use of talcum powder products and  5 ovarian cancer?  6 A. That's correct.  7 Q. Dr. Muscat, is it your view  8 that cosmetic talc is safe to use?  9 MR. TISI: Objection.  10 THE WITNESS: Yes.  11 BY MR. HEGARTY:  12 Q. And are talcum powder  13 products a carcinogen?  14 MR. TISI: Objection.  15 THE WITNESS: No.  16 BY MR. HEGARTY:  17 Q. Just very briefly, you were  18 asked about a 2000 proposal that  19 Dr. Huncharek made to J&amp;J. Do you recall  20 that? And that had your name on it?  21 A. Yes.  22 Q. It was represented to you  23 that that proposal was -- actually became  24 the 2003 paper. Have you been shown that</p>	<p style="text-align: right;">Page 600</p> <p>1 Q. If you look at the document  2 that was actually attached to that  3 document. Isn't that in fact a  4 confidentiality agreement, and that  5 plaintiffs' counsels statement that it  6 was a consulting agreement is a  7 misrepresentation?  8 MR. TISI: Objection.  9 THE WITNESS: It does say  10 underlined "confidentiality  11 agreement."  12 BY MR. HEGARTY:  13 Q. So the actual agreement was  14 not a consulting agreement. It was a  15 confidentiality agreement; isn't that  16 right?  17 A. It's a confidentiality  18 agreement.  19 Q. You were asked earlier about  20 folks providing comments to your papers,  21 that then might be considered in  22 publishing those papers. Do you recall  23 those questions?  24 A. Yes.</p>
<p style="text-align: right;">Page 599</p> <p>1 that proposal was in any way linked to  2 the 2003 paper?  3 A. No.  4 MR. TISI: Objection.  5 BY MR. HEGARTY:  6 Q. Do you have Exhibit  7 Number 11? Would you look at Exhibit  8 Number 11, Dr. Muscat?  9 A. I'm sorry.  10 Q. Counsel for plaintiff  11 represented to you --  12 MR. TISI: What was the  13 number?  14 THE WITNESS: It's Johnson &amp;  15 Johnson consulting agreement.  16 MR. TISI: I know what it  17 is. Thank you.  18 BY MR. HEGARTY:  19 Q. That was represented to you  20 by counsel for plaintiff to be a  21 consulting agreement between American  22 Health Foundation and J&amp;J. Do you recall  23 that representation being made?  24 A. Yes, I do.</p>	<p style="text-align: right;">Page 601</p> <p>1 Q. When you send out papers to  2 be -- for possible publication, do they  3 go to peer reviewers, is that correct?  4 A. That is correct.  5 Q. And do peer reviewers  6 provide comments?  7 A. Yes, they do.  8 Q. And sometimes are those  9 comments considered by the authors?  10 A. Yes, they are.  11 Q. And are peer reviewers ever  12 included as authors in any paper?  13 A. No.  14 Q. You were also asked about  15 the reason for doing meta-analysis or  16 perhaps the strength of the  17 meta-analysis. Do you recall those  18 questions?  19 A. Yes.  20 Q. Does a meta-analysis in any  21 way do away with bias?  22 A. No.  23 Q. Does it in any way do away  24 with confounding?</p>

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<p>1 A. No.</p> <p>2 Q. So it can be the classic</p> <p>3 case of garbage in, garbage out?</p> <p>4 A. That's correct.</p> <p>5 MR. TISI: Objection.</p> <p>6 BY MR. HEGARTY:</p> <p>7 Q. In fact, the Langseth paper</p> <p>8 that we looked at was a meta-analysis,</p> <p>9 correct?</p> <p>10 A. That's correct.</p> <p>11 Q. And Langseth authors</p> <p>12 concluded in that meta-analysis, that</p> <p>13 there was no -- to be accurate, that,</p> <p>14 "The current body of experimental and</p> <p>15 epidemiological evidence is insufficient</p> <p>16 to establish a causal association between</p> <p>17 perineal use of talc and ovarian cancer</p> <p>18 risk."</p> <p>19 And that's from their</p> <p>20 meta-analysis, correct?</p> <p>21 MR. TISI: Objection.</p> <p>22 THE WITNESS: That's</p> <p>23 correct.</p> <p>24 BY MR. HEGARTY:</p>	<p>1 correct.</p> <p>2 MR. HEGARTY: Off the record</p> <p>3 real quick to see if I'm done.</p> <p>4 THE VIDEOGRAPHER: Going off</p> <p>5 the record. 7:09 p.m.</p> <p>6 (Brief pause.)</p> <p>7 THE VIDEOGRAPHER: We are</p> <p>8 back on record. 7:10 p.m.</p> <p>9 BY MR. HEGARTY:</p> <p>10 Q. Dr. Muscat, just a few more</p> <p>11 questions. Do you recall being shown a</p> <p>12 PowerPoint slide that indicated that the</p> <p>13 pooled analysis of studies showed a</p> <p>14 33 percent increased risk of ovarian</p> <p>15 cancer. Do you recall that slide?</p> <p>16 A. Yes.</p> <p>17 Q. In fact, do the cohort</p> <p>18 studies that were done show no increased</p> <p>19 risk between talc use and ovarian cancer?</p> <p>20 A. That's correct.</p> <p>21 Q. And do the hospital studies</p> <p>22 that were done show no increased risk</p> <p>23 between talc use and ovarian cancer?</p> <p>24 A. That's correct.</p>
Page 603	Page 605
<p>1 Q. So it's not just</p> <p>2 Dr. Huncharek saying that there's no</p> <p>3 causal association between talc use and</p> <p>4 ovarian cancer from a meta-analysis.</p> <p>5 It's members of the IARC working group,</p> <p>6 correct?</p> <p>7 A. That's correct.</p> <p>8 Q. You were also asked about</p> <p>9 Exhibit Number 26. Would you pull</p> <p>10 Exhibit Number 26 out, please.</p> <p>11 Okay. Exhibit 26 is</p> <p>12 represented to be a proposal submitted</p> <p>13 for J&amp;J. Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. Does that proposal</p> <p>16 submitted -- who was that proposal</p> <p>17 actually submitted to?</p> <p>18 A. Personal Care Products</p> <p>19 Council.</p> <p>20 Q. So was that a</p> <p>21 misrepresentation made that that was a</p> <p>22 proposal submitted to J&amp;J.</p> <p>23 MR. TISI: Objection.</p> <p>24 THE WITNESS: That's</p>	<p>1 Q. And do approximately half of</p> <p>2 the population based case-control studies</p> <p>3 show no increased risk between talc use</p> <p>4 and ovarian cancer?</p> <p>5 A. That's correct.</p> <p>6 Q. So is it improper to say</p> <p>7 that the pooled analysis of studies show</p> <p>8 a 33 percent increase in risk between</p> <p>9 talc use and ovarian cancer?</p> <p>10 A. Yes.</p> <p>11 MR. TISI: I'm going to</p> <p>12 object that this is way outside</p> <p>13 the scope on issues related to</p> <p>14 expert testimony. It goes beyond</p> <p>15 the time frame that I talked</p> <p>16 about.</p> <p>17 BY MR. HEGARTY:</p> <p>18 Q. You were asked about Dr. --</p> <p>19 MR. TISI: I'm not actually</p> <p>20 finished, Counsel.</p> <p>21 MR. HEGARTY: Oh, I'm sorry.</p> <p>22 Go ahead.</p> <p>23 MR. TISI: And the second</p> <p>24 part of it is you are required, if</p>

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<p style="text-align: right;">Page 606</p> <p>1 you're going to do a direct 2 examination, to provide an expert 3 disclosure, and under the pretrial 4 order entered, you give us notice 5 if you do a direct examination. 6 So I object on those 7 grounds. 8 MR. HEGARTY: We did serve a 9 cross-notice prior to the 10 deposition. 11 MR. TISI: Cross-notice does 12 not -- you have an obligation to 13 provide something in connection 14 with the -- the order provides a 15 time frame that you're supposed to 16 let us know that. You served that 17 last night. And cross-notice is 18 not an intent to take a 19 preservation deposition, nor is it 20 a skirting around the rules of 21 Rule 26, which requires an expert 22 disclosure if he's going to do 23 that. 24 I specifically limited my</p>	<p style="text-align: right;">Page 608</p> <p>1 with that analysis and dispute 2 that this is an expert deposition 3 examination. 4 MR. TISI: You asked -- 5 MR. HEGARTY: This is 6 completely consistent with the 7 scope of the deposition -- 8 MR. TISI: You asked some 9 very broad questions about 10 causation which go beyond the 2011 11 time frame. 12 MR. HEGARTY: I think they 13 are consistent with what you 14 asked. 15 BY MR. HEGARTY: 16 Q. Doctor, just a few more 17 questions. You were asked about some 18 basic points against causation, lack of 19 dose-response, lack of biologic 20 plausibility, lack of consistency between 21 the studies, and uncontrolled 22 confounding. 23 Do you recall those 24 questions?</p>
<p style="text-align: right;">Page 607</p> <p>1 time frame until 2011 because that 2 was his involvement with the 3 published peer-reviewed literature 4 as well as providing reports to 5 the FDA and others. 6 MR. HEGARTY: Just for the 7 record, we did not receive the 8 notice until Friday, which I think 9 also is required to be served much 10 earlier than last Friday. 11 MR. TISI: For the record, 12 this deposition has been set up 13 for at least a month. And so you 14 knew about this deposition long 15 ahead. 16 If you intended to provide 17 us with a direct examination and 18 particularly an expert direct 19 examination, you had an 20 obligation, A, to disclose it; 21 and, B, provide a Rule 26 22 statement, neither which you have 23 done. 24 MR. HEGARTY: We don't agree</p>	<p style="text-align: right;">Page 609</p> <p>1 A. Yes. 2 Q. Are you also aware that the 3 association, to the extent there has been 4 reported one, is weak? 5 A. That's correct. 6 MR. TISI: Objection. 7 BY MR. HEGARTY: 8 Q. And has the cell data 9 reported to be negative showing no causal 10 link between talc use and ovarian cancer? 11 MR. TISI: Objection basis. 12 THE WITNESS: Yes. 13 BY MR. HEGARTY: 14 Q. Have the animal studies been 15 shown to show no link between talc use 16 and ovarian cancer? 17 A. That's correct. 18 MR. TISI: Objection. 19 Beyond the scope. 20 BY MR. HEGARTY: 21 Q. You were also asked about 22 the 2003 Huncharek study and in 23 particular some of the other articles 24 that he cited. Would you need to have a</p>

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<p style="text-align: right;">Page 610</p> <p>1 chance to review all of the articles in 2 detail before you could properly compare 3 what he was doing or citing in that study 4 versus what he was reporting in his 5 paper? 6 A. Yes, I think that would be 7 fair. 8 Q. Did you have a chance to do 9 that tonight? 10 A. No. 11 Q. And would you also want to 12 do the same thing with regard to the 13 diaphragm study, have a chance to review 14 all the study -- articles and determine 15 whether those articles, what data was 16 pulled from those and how it was analyzed 17 and how it was put in the paper? 18 A. Yes. 19 Q. Have you had a chance to do 20 that tonight? 21 A. No. 22 Q. With regard to both those 23 papers, who was the primary author? 24 A. Dr. Huncharek.</p>	<p style="text-align: right;">Page 612</p> <p>1 aware of. 2 BY MR. HEGARTY: 3 Q. Any response or change to a 4 protective effect from NSAIDs or aspirin? 5 A. No. 6 Q. Any findings of cancer of 7 the cervix, vagina, or uterus associated 8 with those products? 9 A. No. 10 Q. Again, Dr. Muscat, from your 11 review of the literature, is -- are 12 talcum powder products safe to use? 13 MR. TISI: Objection. 14 THE WITNESS: Yes. 15 MR. TISI: Expert testimony. 16 MR. HEGARTY: That's all the 17 questions I have. Thank you. 18 THE VIDEOGRAPHER: Going off 19 the record. 7:16 p.m. 20 (Brief pause.) 21 THE VIDEOGRAPHER: Back on 22 record 7:19 p.m. 23 - - - 24 EXAMINATION</p>
<p style="text-align: right;">Page 611</p> <p>1 Q. And you were also asked at 2 the end about biologic plausibility. Do 3 you recall those questions? 4 A. Yes, I do. 5 Q. And talc, with whatever is 6 in it, has been -- that has been studied 7 in these -- in the various studies that 8 we talked about here today. Have those 9 studies showed any biologic plausibility 10 between talc use and ovarian cancer? 11 MR. TISI: Objection. 12 THE WITNESS: No. 13 MR. TISI: Objection. 14 BY MR. HEGARTY: 15 Q. Any reports of inflammation 16 in the ovaries following talc use? 17 MR. TISI: Objection. 18 THE WITNESS: Not that I'm 19 aware of. 20 BY MR. HEGARTY: 21 Q. Finding a foreign body 22 response? 23 MR. TISI: Objection. 24 THE WITNESS: Not that I'm</p>	<p style="text-align: right;">Page 613</p> <p>1 - - - 2 BY MR. TISI: 3 Q. So, Doctor -- so, Doctor, I 4 am going to ask you some follow-up 5 questions to what J&amp;J's counsel, 6 Mr. Hegarty -- and again, you've met 7 Mr. Hegarty before? 8 A. Yes. 9 Q. You've known him for years, 10 right? 11 A. That's correct. 12 Q. You probably met with him 13 before your deposition today, correct? 14 A. That's correct. 15 Q. He's paying your bills, 16 correct? 17 MR. HEGARTY: Objection to 18 form. 19 MR. HUDSON: Objection to 20 form. 21 BY MR. TISI: 22 Q. He's paying for your time? 23 A. I am compensated for my 24 time.</p>

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<p>1 Q. By J&amp;J?</p> <p>2 A. That's correct.</p> <p>3 Q. All right. So did you spend</p> <p>4 any time for him prepping for your</p> <p>5 deposition today?</p> <p>6 A. Excuse me?</p> <p>7 Q. Did you spend any time</p> <p>8 preparing for your deposition today with</p> <p>9 Mr. Hegarty?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. How much time?</p> <p>12 A. There were I believe nine</p> <p>13 sessions in Hershey.</p> <p>14 Q. Nine sessions in Hershey</p> <p>15 before you showed up here today. How</p> <p>16 many hours was that?</p> <p>17 MR. SILVER: Objection.</p> <p>18 Outside the scope.</p> <p>19 MR. HEGARTY: Objection.</p> <p>20 THE WITNESS: For each</p> <p>21 session?</p> <p>22 BY MR. TISI:</p> <p>23 Q. Yeah.</p> <p>24 A. It varied. So anywhere from</p>	<p>1 A. Yes, I did.</p> <p>2 Q. Okay. Was he representing</p> <p>3 you at the time?</p> <p>4 MR. HEGARTY: Objection to</p> <p>5 form.</p> <p>6 THE WITNESS: Mr. Hudson is</p> <p>7 my --</p> <p>8 MR. HUDSON: I represent</p> <p>9 Dr. Muscat.</p> <p>10 BY MR. TISI:</p> <p>11 Q. Okay. So are you going to</p> <p>12 tell us what documents you reviewed with</p> <p>13 Mr. Hegarty?</p> <p>14 MR. HEGARTY: I will</p> <p>15 instruct Dr. Muscat not to respond</p> <p>16 to the extent you are asking him</p> <p>17 about -- want him to tell you what</p> <p>18 documents we looked at, on the</p> <p>19 grounds that they're protected by</p> <p>20 the work product and the</p> <p>21 consulting expert privilege. If</p> <p>22 you want to show him a document</p> <p>23 and ask him whether he saw it and</p> <p>24 when he saw it, you're certainly</p>
Page 615	Page 617
<p>1 three to maybe six hours.</p> <p>2 Q. Three to six hours nine</p> <p>3 times. In what time frame?</p> <p>4 A. Over five, six weeks.</p> <p>5 Q. Five, six weeks. Nine</p> <p>6 times. Five, six weeks.</p> <p>7 And were you missing</p> <p>8 classes, get your substitute to take</p> <p>9 those classes as well?</p> <p>10 MR. SILVER: Objection.</p> <p>11 Outside the scope.</p> <p>12 MR. HEGARTY: Same</p> <p>13 objection.</p> <p>14 THE WITNESS: I was missing</p> <p>15 time from work.</p> <p>16 BY MR. TISI:</p> <p>17 Q. You was -- you were or were</p> <p>18 not?</p> <p>19 A. I was.</p> <p>20 MR. HEGARTY: Objection to</p> <p>21 form.</p> <p>22 BY MR. TISI:</p> <p>23 Q. So -- and did you go over</p> <p>24 documents with him?</p>	<p>1 allowed to do that.</p> <p>2 MR. HUDSON: I join in the</p> <p>3 instruction on the basis of</p> <p>4 attorney/client privilege.</p> <p>5 MR. TISI: I'm not asking</p> <p>6 for communications with you.</p> <p>7 BY MR. TISI:</p> <p>8 Q. I'm asking for</p> <p>9 communications with counsel for Johnson &amp;</p> <p>10 Johnson, who is not representing you,</p> <p>11 correct, although they're paying your</p> <p>12 bills and paying for Mr. Hudson?</p> <p>13 A. That's correct.</p> <p>14 MR. HUDSON: Objection to</p> <p>15 form.</p> <p>16 BY MR. TISI:</p> <p>17 Q. Nine hours, three to</p> <p>18 six hours a day that's 27 hours. A lot</p> <p>19 of time over the past five or six weeks,</p> <p>20 right?</p> <p>21 MR. SILVER: Objection.</p> <p>22 Move to strike.</p> <p>23 MR. HEGARTY: Objection to</p> <p>24 form.</p>

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<p style="text-align: right;">Page 618</p> <p>1 THE WITNESS: It has been a 2 lot of time. 3 BY MR. TISI: 4 Q. It has been a lot of time. 5 All right. So let me ask you this. You 6 were asked some questions by Mr. Hegarty 7 about communications with Johnson &amp; 8 Johnson about the white papers, correct? 9 A. That's correct. 10 Q. Remember he said we didn't 11 speak to Johnson &amp; Johnson, we didn't 12 speak to any -- did you speak to any of 13 them, do you know what they did to your 14 papers, and all that, correct? 15 MR. HEGARTY: Objection to 16 form. 17 THE WITNESS: That is 18 correct. 19 BY MR. TISI: 20 Q. Well, that's because the 21 confidentiality agreement required you to 22 be speaking to the lawyers, right? 23 MR. HEGARTY: Objection to 24 form.</p>	<p style="text-align: right;">Page 620</p> <p>1 fact, the primary point of communication 2 was Dr. Huncharek, right? 3 MR. HEGARTY: Objection to 4 form. 5 BY MR. TISI: 6 Q. For you? 7 A. That's correct. 8 Q. So you communicated to 9 Dr. Huncharek, but to the extent to which 10 you knew that you were supposed to have 11 communications with Dr. Huncharek to the 12 lawyers, who would then communicate back 13 and forth with their clients, whether it 14 be Mr. -- Imerys, if they were the 15 official client or the other contractor 16 which was J&amp;J, correct? 17 MR. HUDSON: Objection to 18 form. 19 MR. SILVER: Objection to 20 form. 21 THE WITNESS: Dr. Huncharek 22 did the communications with 23 Crowell &amp; Moring. 24 BY MR. TISI:</p>
<p style="text-align: right;">Page 619</p> <p>1 BY MR. TISI: 2 Q. Confidentiality agreement 3 number 31 has information you were to be 4 submitting to the lawyers, the white 5 papers, privileged and confidential, 6 prepared at the request of legal counsel, 7 right? 8 MR. HEGARTY: Objection to 9 form. 10 THE WITNESS: I'm sorry. 11 Can you repeat that? 12 BY MR. TISI: 13 Q. Yeah. Go to page -- go to 14 second page. It has a confidentiality 15 agreement. And you knew that all 16 communications with Johnson &amp; Johnson and 17 Imerys were supposed to be through the 18 lawyers, correct? 19 MR. HEGARTY: Objection to 20 form. 21 BY MR. TISI: 22 Q. At that time. 23 A. At that time. 24 Q. And so all of your -- in</p>	<p style="text-align: right;">Page 621</p> <p>1 Q. Right. So you know the 2 issues of, you know, filtering things 3 through law firms. That's exactly what 4 you were doing, correct? 5 MR. SILVER: Objection to 6 form. 7 MR. HUDSON: Objection to 8 form. 9 BY MR. TISI: 10 Q. You were filtering the 11 information back and forth to these 12 defendants going through the law firm; is 13 that correct? 14 MR. SILVER: Objection to 15 form. 16 THE WITNESS: No. 17 BY MR. TISI: 18 Q. Okay. If you didn't have 19 any direct contacts with Mr. Hegarty's 20 client, you had direct contacts with the 21 lawyers representing Mr. Hegarty's 22 clients? 23 MR. HUDSON: Objection to 24 form.</p>

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<p style="text-align: right;">Page 622</p> <p>1 MR. SILVER: Objection to 2 form. 3 BY MR. TISI: 4 Q. Correct? 5 A. No. 6 Q. No, that wasn't true? So 7 most of the communications, I thought you 8 just said went through Crowell &amp; Moring, 9 according to the contract? 10 MR. HEGARTY: Objection to 11 form. 12 THE WITNESS: I'm not sure 13 what communications you are 14 referring to. 15 BY MR. TISI: 16 Q. Well, when the papers were 17 sent around, when the draft white papers 18 were sent around, they were sent to 19 Crowell &amp; Moring, were they not? 20 MR. HEGARTY: Objection to 21 form. 22 THE WITNESS: I assume they 23 were. 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 624</p> <p>1 form. 2 THE WITNESS: I see that. 3 BY MR. TISI: 4 Q. Entitled "task deliverables 5 from Dr. Huncharek" -- excuse me -- 6 "Dr. Huncharek and Muscat," correct? 7 A. I see that. Yes. 8 Q. So the information was sent 9 to the law firm and then forwarded to 10 Imerys and J&amp;J, correct? 11 MR. HEGARTY: Objection to 12 form. 13 BY MR. TISI: 14 Q. Or in this case Luzenac? 15 A. Yes. 16 Q. All right. That's the way 17 the communication went, right? Send the 18 papers to the law firm, the law firm then 19 sends it to the -- to the companies, and 20 anything went back, went back to the law 21 firm, went to Mr. -- to Dr. Huncharek. 22 And you don't know where it came from, 23 right? 24 MR. HEGARTY: Objection to</p>
<p style="text-align: right;">Page 623</p> <p>1 Q. Right. And were they sent 2 directly to J&amp;J? 3 A. I have no knowledge of that. 4 Q. Okay. You saw a document 5 where there was an e-mail from Ridge Hall 6 with a stack of documents. Do you 7 remember with red lines and the papers 8 that you had drafted, right? 9 MR. HEGARTY: Objection to 10 form. 11 THE WITNESS: I'm sorry. 12 Which -- 13 BY MR. TISI: 14 Q. There was a thick document 15 in there. I think it was Exhibit 16 Number -- Number 38. 17 Go to Exhibit 20, please. 18 It's this one here. It's on the screen. 19 A. Oh, sorry. 20 Q. Okay. This was an e-mail 21 where you saw that Dr. -- that Crowell &amp; 22 Moring was sending your work to J&amp;J and 23 to Imerys, correct? 24 MR. HEGARTY: Objection to</p>	<p style="text-align: right;">Page 625</p> <p>1 form. 2 MR. SILVER: Objection to 3 form. 4 BY MR. TISI: 5 Q. And it's on the privilege 6 log, and we can't get a copy of it. 7 MR. HUDSON: Objection to 8 form. 9 MR. HEGARTY: Objection to 10 form. 11 THE WITNESS: I'm not sure 12 what the question is. 13 BY MR. TISI: 14 Q. Well, the question is, 15 Doctor, the whole -- this whole scheme 16 that was set up of going back and forth 17 between the law firm was designed to not 18 have you have direct contact with the 19 lawyers and to preserve the 20 confidentiality of what you were doing, 21 correct? 22 MR. SILVER: Objection. 23 Move to strike. Beyond the scope. 24 Asked and answered.</p>

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<p>1 MR. HEGARTY: Objection to 2 form. 3 MR. HUDSON: Objection to 4 form. 5 BY MR. TISI: 6 Q. It was a scheme. You had 7 a -- you had a -- 8 MR. TISI: Turn on the -- 9 can we turn this on, please. 10 BY MR. TISI: 11 Q. You had the law firm in the 12 middle, Crowell &amp; Moring. You had 13 Huncharek, Muscat, Imerys, and J&amp;J. 14 Now, you made it pretty 15 clear that you weren't communicating 16 directly with J&amp;J and Imerys about your 17 white papers, right? 18 MR. HEGARTY: Objection to 19 form. 20 THE WITNESS: That's 21 correct. 22 BY MR. TISI: 23 Q. Okay. Most of the 24 information you had went to Dr. Huncharek</p>	<p>1 &amp; Moring, correct? 2 A. I assume so. 3 Q. Okay. They did not go 4 directly -- and the information, we saw 5 that there was -- there were privilege 6 logs where we don't get the 7 communications between you -- 8 MR. HUDSON: Objection to 9 form. 10 BY MR. TISI: 11 Q. -- you and Crowell &amp; Moring, 12 correct? 13 A. I don't know what that 14 means. 15 Q. Right. Right. So there are 16 documents that we didn't get because they 17 went to Crowell &amp; Moring. And you don't 18 know what Crowell &amp; Moring was talking 19 about with Imerys and J&amp;J, do you? 20 MR. HUDSON: Objection to 21 form. 22 MR. SILVER: Objection to 23 form. 24 THE WITNESS: That's</p>
Page 627	Page 629
<p>1 correct? 2 A. So I'm not sure what you're 3 referring to. There was no scheming in 4 anything. I haven't schemed in anything. 5 So I really object to whatever it is 6 you're implying. I have not schemed in 7 anything. 8 Q. Well, the whole purpose of 9 this -- of this -- 10 A. I really object to this. 11 But go ahead. 12 Q. You can object all you want, 13 sir. 14 A. Yeah, fine. 15 Q. Okay. So this -- you sent 16 your information -- 17 A. I don't know what you're 18 referring to, my information. 19 Q. The white papers. The white 20 papers that you and Dr. -- first of all, 21 who wrote the white papers, you or 22 Dr. Huncharek? 23 A. Dr. Huncharek. 24 Q. Okay. They went to Crowell</p>	<p>1 correct. 2 BY MR. TISI: 3 Q. All right. So now, let me 4 ask you this. You're a tenured 5 professor, correct? 6 A. That's correct, yes. 7 Q. Is that correct? Right. 8 You have an obligation to publish, 9 correct? That's one of the requirements 10 to publish? 11 A. Yes. 12 Q. Did you -- you made -- and 13 you talked with Mr. Hegarty about all of 14 the articles that you published and book 15 chapters on different forms of cancer. 16 And you talked about your ovarian cancer 17 talc publications, correct? 18 A. Yes. 19 (Document marked for 20 identification as Exhibit 21 Muscat-37.) 22 BY MR. TISI: 23 Q. I'm going to mark as Exhibit 24 Number 37, and I'm going to give it to</p>

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<p style="text-align: right;">Page 630</p> <p>1 you. And I'm going to ask you to show me 2 the ones that you made a large -- a lot 3 of points about I wasn't the primary 4 author here, I wasn't the primary author 5 there. 6 I want you to write next to 7 each one of them which ones Dr. Huncharek 8 was the primary author on and which one 9 you were. And just write Hs next to -- 10 A. Okay. 11 Q. -- Hs and Ms. 12 A. Okay. (Witness complies.) 13 Q. Let me see it, please. The 14 only one that you were the primary author 15 on is the letter to the editor in 2005 16 that we haven't talked about, about three 17 paragraphs, right? 18 A. That's correct. 19 Q. And the other one is 2008, 20 The Critical Review, you were the primary 21 author on that one. 22 A. That's right. 23 Q. Everything else was written 24 by Dr. Huncharek primarily?</p>	<p style="text-align: right;">Page 632</p> <p>1 Q. Did you represent to Penn 2 State that these were your publications? 3 MR. HEGARTY: Objection to 4 form. 5 BY MR. TISI: 6 Q. Did you -- that you were -- 7 that you were the primary authors on any 8 of these publications that you listed as 9 Dr. Huncharek's? 10 A. Did I represent to Penn 11 State? 12 Q. Mm-hmm, yes. Did you tell 13 Penn State that Dr. Huncharek wrote the 14 majority of any of the papers that are 15 published? 16 A. I haven't gotten into a 17 conversation with anyone at Penn State 18 about... 19 Q. Okay. All right. Now, you 20 were asked a lot of questions about, as 21 you sit here today is talc safe, as 22 you -- you know, does the totality of the 23 evidence, animal studies, and all that. 24 I didn't ask you any of</p>
<p style="text-align: right;">Page 631</p> <p>1 A. For the red marked ones? 2 Q. Yes. 3 A. That's correct. 4 Q. Okay. Now, of the 2007 5 article on diaphragms, what percentage of 6 the work was actually done by 7 Dr. Huncharek as opposed to you? 8 A. The majority of it. 9 Q. When we say majority, 10 90 percent, 50 percent? 11 A. I couldn't give you a 12 percentage. I mean he was the primary 13 author. He wrote -- he wrote the 14 article. 15 Q. Okay. Same thing with the 16 2009 article? 17 A. That's correct. 18 Q. The article, the white 19 paper? 20 A. Yes. The white paper, 21 right. 22 Q. The 2011 article, the same 23 thing? 24 A. Yes.</p>	<p style="text-align: right;">Page 633</p> <p>1 those questions, did I? Did I ask you 2 about animal studies? 3 MR. HEGARTY: Objection to 4 form. 5 THE WITNESS: I don't recall 6 specifically. 7 BY MR. TISI: 8 Q. Did I ask you your opinion 9 about, what you sit -- what you sit here 10 today, what your opinion is about talc 11 and ovarian cancer? Did I ask you any of 12 those questions? 13 A. You asked me about 14 causation. 15 Q. I asked you about causation 16 as it relates to something that you wrote 17 to the FDA in 2011, correct? 18 A. That's correct. 19 Q. I asked you what you were 20 representing in the published literature 21 and what you were talking about to 22 doctors and the FDA, et cetera, correct? 23 MR. HEGARTY: Objection to 24 form.</p>



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<p style="text-align: right;">Page 634</p> <p>1 BY MR. TISI: 2 Q. I didn't ask you what your 3 opinion was as a litigation expert here 4 with Mr. Hegarty, did I? 5 MR. HEGARTY: Objection to 6 form. 7 MR. SILVER: Objection. 8 Misstates the testimony. 9 THE WITNESS: I don't know 10 the differences. 11 BY MR. TISI: 12 Q. Okay. 13 A. Okay. 14 Q. So, let me ask you this. 15 You were asked about the Langseth 16 article. Can you pull that out, please, 17 sir? 18 A. I'm sorry, which exhibit? 19 Q. Exhibit 36. Now, 20 Mr. Hegarty -- I'm going to point you to 21 some of the things that Mr. Hegarty 22 didn't tell -- ask you about the Langseth 23 article. First of all, the Langseth 24 article is not an IARC paper, correct?</p>	<p style="text-align: right;">Page 636</p> <p>1 form. 2 THE WITNESS: So I don't 3 recall coming across any 4 publications of his that says 5 that. 6 BY MR. TISI: 7 Q. I actually didn't ask you 8 that. I asked you, do you understand 9 that Dr. Siemietycki believes that 10 evidence since 2007 has added to the 11 strength of the evidence supporting a 12 causal inference? 13 MR. HUDSON: Objection to 14 form. 15 MR. HEGARTY: Objection to 16 form. 17 THE WITNESS: Let me 18 clarify. I haven't spoken with 19 him. So I'm unaware of anything. 20 BY MR. TISI: 21 Q. All right. Now, in his 22 article in 2007, on Page 2, you were 23 asked the question. And I'm going to put 24 it right down here. You were asked about</p>
<p style="text-align: right;">Page 635</p> <p>1 A. Well, I would say that it 2 does represent IARC. There is an -- in 3 the acknowledgment section, it says, "The 4 work reported in this paper was initiated 5 while SH, JS and EW were part of an IARC 6 monograph working group." 7 Q. Right. 8 A. Right. 9 Q. But this is not an official 10 IARC paper, is it? 11 A. It's a -- it's an 12 independent paper. That's correct. 13 Q. Right. And this is 2007, 14 correct? 15 A. That's correct. 16 Q. Have you been made aware 17 that Dr. Siemietycki has indicated from 18 2007 forward, that the association and 19 the evidence in favor of causation has 20 strengthened and that he believes that 21 talc is a likely cause of ovarian cancer? 22 MR. HEGARTY: Objection to 23 form. 24 MR. HUDSON: Objection to</p>	<p style="text-align: right;">Page 637</p> <p>1 the sentence, "The evidence" -- let me 2 read the whole paragraph. 3 He writes, "To summarize, 4 the evidence in favor of association, a 5 very large number of studies have found 6 that women who use talc experienced 7 excess risk of ovarian cancer. Some 8 results were statistically significant 9 and some were not." 10 So he's indicating, on 11 balance, there is epidemiologic favor, 12 favors causation, right? 13 MR. HUDSON: Objection to 14 form. 15 BY MR. TISI: 16 Q. Epidemiological evidence 17 favors association? 18 MR. HUDSON: Same objection. 19 BY MR. TISI: 20 Q. Let me rephrase the 21 question. I apologize. I'm trying to go 22 fast here. Let me just read what he 23 says. 24 A. Okay.</p>

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<p style="text-align: right;">Page 638</p> <p>1 Q. "To summarize the evidence 2 in favor of an association, a very large 3 number of studies have found that women 4 who used talc experienced an excess" -- 5 "an excess risk of ovarian cancer. Some 6 results were statistically significant 7 and some were not." 8 Correct? 9 A. I see that. 10 Q. And he's indicating that the 11 very large number of studies are -- 12 consistently show an excess risk of 13 ovarian cancer associated with talc, 14 correct? 15 MR. HUDSON: Objection to 16 form. 17 MR. HEGARTY: Objection to 18 form. 19 THE WITNESS: So I think, so 20 each one of these studies there's 21 a lot of different calculations. 22 So I'd have to -- I'm not exactly 23 sure which -- 24 BY MR. TISI:</p>	<p style="text-align: right;">Page 640</p> <p>1 issue, you proposed a case-control study, 2 correct? 3 A. That's correct. 4 Q. And that was -- we marked 5 that as an exhibit. And you proposed 6 that in the 1990s, correct? 7 A. That's correct. 8 Q. You didn't propose a cohort 9 study, correct? 10 MR. HEGARTY: Objection. 11 BY MR. TISI: 12 Q. Correct? 13 A. That's correct. 14 Q. In fact today, you -- up 15 until today you haven't gone to -- you 16 have worked with Mr. Hegarty for years, 17 have you gone to them and said, "Let's do 18 a cohort study. I'll design it for you." 19 MR. HEGARTY: Objection to 20 form. And I'll instruct him not 21 to respond to the extent it would 22 reveal communications with him in 23 his capacity as an expert. 24 BY MR. TISI:</p>
<p style="text-align: right;">Page 639</p> <p>1 Q. I'm just asking you what he 2 says? 3 A. Yes, okay. 4 Q. "There was some indication 5 in the cohort study of an increase in 6 serious tumors." 7 Correct? 8 MR. HEGARTY: Objection. 9 THE WITNESS: Yes, that's 10 correct. 11 BY MR. TISI: 12 Q. And that's true, correct? 13 MR. HEGARTY: Objection to 14 form. 15 THE WITNESS: In the initial 16 report of the Nurses Health Study, 17 that is correct. 18 BY MR. TISI: 19 Q. Now, in fact, counsel asked 20 you about cohort studies, and I just want 21 to be absolutely clear. When you were 22 given the opportunity to actually make a 23 proposal to study talc and design the 24 best study you can think of to study that</p>	<p style="text-align: right;">Page 641</p> <p>1 Q. Have you -- have you ever 2 gone to J&amp;J and said to them, you know, 3 gee, J&amp;J maybe you ought to do the study 4 that I proposed back in the 1990s? 5 MR. HEGARTY: Objection to 6 form. 7 THE WITNESS: No. 8 BY MR. TISI: 9 Q. Did you ever go to them and 10 say, maybe we should do a different 11 study, maybe a cohort study? 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: No, I haven't 15 said that. 16 BY MR. TISI: 17 Q. Okay. Have you ever gone to 18 J&amp;J and said, maybe you ought to do a 19 hospital study? 20 MR. HEGARTY: Objection to 21 form. 22 BY MR. TISI: 23 Q. A case-control hospital 24 study?</p>

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Page 642	Page 644
<p>1 A. That was the first time back 2 in the 1990s, right. 3 Q. Okay. Now, the next 4 sentence that Mr. Hegarty didn't ask you. 5 It says, "On balance" -- the next 6 paragraph -- "the epidemiologic evidence 7 suggest the use of cosmetic talc in the 8 perineal area may be associated with an 9 ovarian cancer risk, the mechanism of 10 carcinogenicity may be related to 11 inflammation." 12 Correct? 13 MR. HEGARTY: Objection to 14 form. 15 THE WITNESS: That's what it 16 says, yes. 17 BY MR. TISI: 18 Q. At this time -- well, let's 19 keep going. 20 The next page says, "What's 21 the study add?" This is a summary of the 22 study. Some studies have this, correct? 23 A. That's correct. 24 Q. Dr. Siemietycki says, "The</p>	<p>1 Q. And he focuses specifically 2 on the consistency of the studies, 3 something that you disputed? 4 A. You have to say consistently 5 with regard to -- with regard to what? 6 So I'm not sure exactly. 7 I don't -- is he referring 8 to dose-response relationships? I don't 9 think there's consistency in that. 10 So I can't speak for him. 11 But I -- I do acknowledge and see what he 12 says up there. 13 MR. TISI: Can we go off the 14 record for a moment. 15 THE VIDEOGRAPHER: Off the 16 record 7:39 p.m. 17 (Brief pause.) 18 THE VIDEOGRAPHER: We're 19 back on record. 7:46 p.m. 20 BY MR. TISI: 21 Q. Were you asked by 22 Mr. Hegarty some questions, overarching 23 questions about things like biologic 24 plausibility. And I'm going to go</p>
Page 643	Page 645
<p>1 epidemiological evidence suggests that 2 the use of cosmetic talc in the perineal 3 area may be associated with ovarian 4 cancer risk. The IARC has classified the 5 use of talc as possibly related to" -- 6 "carcinogenic to human beings." 7 Do you see that? 8 MR. HEGARTY: Objection to 9 form. 10 THE WITNESS: Yes. 11 BY MR. TISI: 12 Q. It goes on to say, "The 13 mechanism of carcinogenicity may be 14 related to inflammation. The paper 15 focuses on the high degree of consistency 16 in the studies accomplished so far and 17 what should focus" -- "should be the 18 focus in the future." 19 Correct? 20 MR. HEGARTY: Objection to 21 form. 22 THE WITNESS: That's what it 23 says, yes. 24 BY MR. TISI:</p>	<p>1 through some of those questions. 2 You were asked whether or 3 not, as you -- whether or not studies as 4 of today showed biologic plausibility 5 between talc use and ovarian cancer. 6 Do you remember that 7 question? 8 A. That's correct. 9 Q. Have you -- first of all, 10 are you a toxicologist? 11 A. No. 12 Q. Are you a pharmacologist? 13 A. No. 14 Q. Are you a geneticist? 15 A. No. 16 Q. An oncologist? 17 A. That's -- no. 18 Q. Have you done any work 19 yourself on issues related to things like 20 inflammation in the ovaries? 21 A. No, I have not. 22 Q. Those are the kinds of 23 things that are done by people who are 24 not PhDs in public health, right?</p>

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<p style="text-align: right;">Page 646</p> <p>1 MR. SILVER: Objection.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Those would be done by</p> <p>4 doctors typically?</p> <p>5 MR. HEGARTY: Objection to</p> <p>6 form.</p> <p>7 THE WITNESS: So it can be</p> <p>8 addressed epidemiologically.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Right. But you haven't done</p> <p>11 that, right?</p> <p>12 A. I haven't done those studies</p> <p>13 myself, that's correct.</p> <p>14 Q. You haven't studied foreign</p> <p>15 body reactions in ovaries with talc, have</p> <p>16 you?</p> <p>17 A. No.</p> <p>18 Q. So you were asked that by</p> <p>19 Mr. Hegarty, and he asked you the</p> <p>20 question. You didn't even study it,</p> <p>21 right?</p> <p>22 MR. SILVER: Objection to</p> <p>23 form.</p> <p>24 MR. HUDSON: Objection to</p>	<p style="text-align: right;">Page 648</p> <p>1 BY MR. TISI:</p> <p>2 Q. Yes, that's correct.</p> <p>3 A. I am finished with the</p> <p>4 published research.</p> <p>5 Q. And you haven't of course</p> <p>6 written an expert report on that, right?</p> <p>7 MR. HEGARTY: Objection to</p> <p>8 form.</p> <p>9 BY MR. TISI:</p> <p>10 Q. Correct? In this federal</p> <p>11 case, MDL?</p> <p>12 A. That's correct.</p> <p>13 Q. Have you been told that you</p> <p>14 were going to be an expert in this MDL?</p> <p>15 MR. HEGARTY: Object and</p> <p>16 instruct the doctor not to respond</p> <p>17 to the extent that it would reveal</p> <p>18 communications with counsel</p> <p>19 pursuant to --</p> <p>20 BY MR. TISI:</p> <p>21 Q. Do you have any --</p> <p>22 MR. HEGARTY: -- the</p> <p>23 consulting privilege.</p> <p>24 If you know apart from that,</p>
<p style="text-align: right;">Page 647</p> <p>1 form.</p> <p>2 THE WITNESS: That's not</p> <p>3 my -- I haven't done that in my</p> <p>4 research area. That's correct.</p> <p>5 BY MR. TISI:</p> <p>6 Q. Change in response to effect</p> <p>7 of NSAIDs or aspirin. You were asked</p> <p>8 that question. Have you looked at the</p> <p>9 literature as of today?</p> <p>10 A. I have looked at the</p> <p>11 literature in the past. That's correct.</p> <p>12 Q. In the past, right?</p> <p>13 A. Yeah.</p> <p>14 Q. So, I mean, you were asked</p> <p>15 questions today by Mr. Hegarty, and you</p> <p>16 were just saying yes, yes, yes. You</p> <p>17 haven't done -- you haven't done the</p> <p>18 research, have you?</p> <p>19 MR. HEGARTY: Objection to</p> <p>20 form.</p> <p>21 MR. HUDSON: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: Have I done</p> <p>24 the personal research?</p>	<p style="text-align: right;">Page 649</p> <p>1 you can answer.</p> <p>2 THE WITNESS: So, no, I</p> <p>3 don't.</p> <p>4 BY MR. TISI:</p> <p>5 Q. You were asked, Dr. Muscat,</p> <p>6 from your review of the literature, is</p> <p>7 talcum powder products safe to use? Do</p> <p>8 you remember that question?</p> <p>9 A. Yes.</p> <p>10 Q. If you were to learn that</p> <p>11 talcum powder contains asbestos, would</p> <p>12 you think it would be safe to use?</p> <p>13 MR. SILVER: Objection to</p> <p>14 form.</p> <p>15 MR. HEGARTY: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: So that's sort</p> <p>18 of a difficult question. If it</p> <p>19 contains asbestos?</p> <p>20 BY MR. TISI:</p> <p>21 Q. Mm-hmm.</p> <p>22 A. I'm sorry. What's the</p> <p>23 question.</p> <p>24 Q. If talcum powder products</p>

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<p style="text-align: right;">Page 650</p> <p>1 contain asbestos today, would it be safe 2 to use? 3 MR. SILVER: Objection to 4 form. 5 THE WITNESS: This is a 6 hypothetical. 7 BY MR. TISI: 8 Q. It is. You were asked the 9 question -- 10 A. Okay. 11 Q. -- so I'm following on it. 12 Yes. 13 A. Okay. 14 Q. If you were to learn that 15 talcum powder products over the past, 16 let's say, couple decades, despite what 17 was in the published literature, 18 contained asbestos, if you would have 19 learned that, would they be safe to use? 20 MR. SILVER: Objection to 21 form. 22 MR. HUDSON: Objection to 23 form. 24 THE WITNESS: I would say</p>	<p style="text-align: right;">Page 652</p> <p>1 MR. HUDSON: Objection to 2 form. 3 MR. HEGARTY: Objection to 4 form. Asked and answered. 5 THE WITNESS: I would agree 6 that I would not talcum -- I would 7 not want asbestos in talcum 8 products. 9 BY MR. TISI: 10 Q. Right. Especially if you 11 were going to apply them -- if women were 12 going to apply them to the perineal area, 13 correct? 14 MR. HEGARTY: Objection to 15 form. 16 THE WITNESS: That's correct 17 I would want not talcum powder in 18 asbestos -- sorry. I would not 19 want asbestos in talcum powder. 20 BY MR. TISI: 21 Q. Especially -- especially 22 since we do know that whatever else is 23 out there, there has been shown to be an 24 increased risk in different studies of</p>
<p style="text-align: right;">Page 651</p> <p>1 that if I -- if I learned that and 2 the concentration was the same in 3 historical studies that looked at 4 the risk of talcum powder and 5 ovarian cancer, I would conclude 6 that -- that the -- there is not a 7 causal association. 8 BY MR. TISI: 9 Q. Right. That wasn't my 10 question though. 11 A. But that's the only way I 12 can answer it. 13 Q. Well, if you were to -- if 14 you were to learn -- I mean, apart from 15 being an expert and being paid by them 16 and all that stuff. Okay. If you were 17 to learn as a doctor -- as a consumer, if 18 you were to learn that the talcum powder 19 products that sit in Kmart right now 20 contain asbestos, would you recommend 21 that they -- would you feel comfortable 22 saying that they were safe? 23 MR. SILVER: Objection to 24 form.</p>	<p style="text-align: right;">Page 653</p> <p>1 ovarian cancer associated with talcum 2 powder products? 3 MR. SILVER: Objection to 4 form. 5 MR. HUDSON: Objection to 6 form. 7 BY MR. TISI: 8 Q. If you knew those two 9 things, Number 1, that there was asbestos 10 in talcum powder products, and Number 2, 11 there were multiple studies that showed 12 an increased risk, that would at least 13 raise for you an index of suspicion, 14 would it not? 15 MR. HUDSON: Objection to 16 form. 17 MR. SILVER: Objection. 18 THE WITNESS: I'd have to 19 look at the studies again and go 20 through all the things that kind 21 of we just talked about. You 22 know, strength of the association, 23 confounding, bias, dose-response 24 relationships. I'd want to look</p>

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<p style="text-align: right;">Page 654</p> <p>1 at it using the methodological</p> <p>2 tools that we use to assess</p> <p>3 causality.</p> <p>4 BY MR. TISI:</p> <p>5 Q. But as you sit here today,</p> <p>6 you would not, if those two things are</p> <p>7 true, you would not be totally</p> <p>8 comfortable putting your reputation on</p> <p>9 the line saying that talcum powder</p> <p>10 products containing asbestos would be</p> <p>11 safe?</p> <p>12 MR. HUDSON: Objection to</p> <p>13 form.</p> <p>14 MR. HEGARTY: Objection to</p> <p>15 form.</p> <p>16 MR. SILVER: Objection to</p> <p>17 the form.</p> <p>18 THE WITNESS: Sorry. Can</p> <p>19 you repeat the question?</p> <p>20 BY MR. TISI:</p> <p>21 Q. Yes. You were asked the</p> <p>22 question by Mr. Hegarty.</p> <p>23 A. Yes.</p> <p>24 Q. As to whether or not talcum</p>	<p style="text-align: right;">Page 656</p> <p>1 BY MR. TISI:</p> <p>2 Q. And you haven't done that</p> <p>3 work, have you?</p> <p>4 MR. HEGARTY: Objection to</p> <p>5 form.</p> <p>6 BY MR. TISI:</p> <p>7 Q. As you sit here today? You</p> <p>8 haven't looked at the studies linking</p> <p>9 ovarian cancer and asbestos, have you?</p> <p>10 MR. HEGARTY: Objection to</p> <p>11 form.</p> <p>12 THE WITNESS: I'm sorry.</p> <p>13 Which studies are you referring to</p> <p>14 specifically?</p> <p>15 BY MR. TISI:</p> <p>16 Q. Have you looked at studies,</p> <p>17 epidemiologic studies involving ovarian</p> <p>18 cancer and asbestos?</p> <p>19 A. I am aware of occupational</p> <p>20 studies.</p> <p>21 Q. Okay. Have you done a</p> <p>22 systematic review of that work?</p> <p>23 A. No.</p> <p>24 MR. HEGARTY: Objection to</p>
<p style="text-align: right;">Page 655</p> <p>1 products were safe based upon what you</p> <p>2 know.</p> <p>3 A. Yes.</p> <p>4 Q. If you were to add to the</p> <p>5 mix of what you know, that talcum powder</p> <p>6 products had asbestos in it, add that</p> <p>7 fact --</p> <p>8 A. Yes.</p> <p>9 Q. -- would you feel</p> <p>10 comfortable saying that talcum powder</p> <p>11 products were safe or would you have to</p> <p>12 do additional research?</p> <p>13 MR. HUDSON: Objection to</p> <p>14 form.</p> <p>15 MR. SILVER: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: So, again, I</p> <p>18 wouldn't want asbestos in talcum</p> <p>19 powder, okay.</p> <p>20 The question of safety as it</p> <p>21 relates to, for example, ovarian</p> <p>22 cancer, I think would have to be</p> <p>23 studied. I would rely on</p> <p>24 epidemiologic studies.</p>	<p style="text-align: right;">Page 657</p> <p>1 form.</p> <p>2 BY MR. TISI:</p> <p>3 Q. Okay. And so my question</p> <p>4 is, in absence of having done that work,</p> <p>5 if you were to learn that talcum powder</p> <p>6 products have and have had asbestos in</p> <p>7 them, you could not sit here today and</p> <p>8 say that talcum products were safe, if</p> <p>9 that was shown to you to be true?</p> <p>10 MR. HUDSON: Objection to</p> <p>11 form.</p> <p>12 MR. HEGARTY: Objection to</p> <p>13 form.</p> <p>14 MR. SILVER: Objection to</p> <p>15 form.</p> <p>16 THE WITNESS: So the only</p> <p>17 thing that I can rely on is the</p> <p>18 epidemiologic evidence, okay. So</p> <p>19 there have been epidemiologic</p> <p>20 studies of powders. Okay. If</p> <p>21 hypothetically, and I don't know</p> <p>22 this, but if hypothetically those</p> <p>23 powders contain some amount --</p> <p>24 trace amount of asbestos, and was</p>

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<p>1 not shown to increase ovarian 2 cancer, that's -- that's what I 3 would rely on. 4 I think IARC did the same 5 thing in terms of their 6 classification that they 7 specifically refer to talc-based 8 powders. 9 So that's -- that's the 10 exposure by which these -- these 11 studies were measured by. 12 BY MR. TISI: 13 Q. Right. But let me be clear. 14 You didn't look at the IARC -- I think it 15 was 2012 or 2015 monograph on asbestos 16 and ovarian cancer, did you? 17 A. I have cursory looked at it. 18 I have not studied it. 19 Q. Right. 20 MR. HUDSON: Counsel, I 21 believe we've run up on the 22 30-minute time frame. 23 MR. TISI: I understand. I 24 understand.</p>	<p>1 answer is. 2 MS. PARFITT: He can answer 3 the question. 4 MR. HEGARTY: It's already 5 past the time. 6 MR. TISI: I want an answer 7 to the question. You -- Counsel, 8 you opened the door so wide. You 9 can't come marching in here and 10 ask him expert questions without 11 an expert report based upon as he 12 sits here today and then expect 13 this not to happen. 14 MR. HEGARTY: You're not 15 supposed to ask the same question 16 and get answer the question three 17 times, and not like it, so then 18 ask another question, which is 19 what you're doing. 20 MR. TISI: That is not true. 21 He's -- 22 MR. HEGARTY: You're getting 23 -- 24 MR. TISI: He's asking the</p>
Page 659	Page 661
<p>1 THE WITNESS: Okay. 2 BY MR. TISI: 3 Q. But in order to render your 4 opinion -- render an opinion, because you 5 were asked general opinions about the 6 safety of talc, you would need to know 7 more about, A, whether talcum powder 8 products have asbestos in it; and, B, 9 what the evidence was that would support 10 an association, correct? 11 MR. HUDSON: Objection to 12 form. Asked and answered. And 13 we're past the time frame. 14 MR. HEGARTY: Yeah, the 15 question has been asked three 16 times. 17 BY MR. TISI: 18 Q. You can answer the question, 19 sir? 20 MR. HEGARTY: Okay. Answer 21 it the same way that you did 22 before. 23 MR. TISI: No, you can 24 answer -- I want to know what his</p>	<p>1 opposite question. 2 MR. HUDSON: We're past the 3 time frame. So let's just agree 4 to go off the record because the 5 examination at this point needs to 6 conclude. 7 MR. TISI: The 8 examination -- I'm going to keep 9 the examination open, and we're 10 going to ask -- we are going to 11 ask to come back, because you 12 opened the door for additional 13 time. 14 MR. SILVER: And note 15 Imerys' objection, and we will 16 strenuously object. 17 MR. TISI: You can 18 strenuously object. You can paint 19 your hair green if you would like 20 to. 21 MR. HUDSON: Let the record 22 reflect we don't agree. 23 MR. SILVER: Off the record. 24 THE VIDEOGRAPHER: Going off</p>

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<p style="text-align: right;">Page 662</p> <p>1 the record this ends today's 2 deposition. We are going off the 3 record at 7:56 p.m. 4 (Document marked for 5 identification as Exhibit 6 Muscat-38.) 7 (Excused.) 8 (Deposition concluded at 9 approximately 7:56 p.m.) 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>	<p style="text-align: right;">Page 664</p> <p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition 4 over carefully and make any necessary 5 corrections. You should state the reason 6 in the appropriate space on the errata 7 sheet for any corrections that are made. 8 After doing so, please sign 9 the errata sheet and date it. 10 You are signing same subject 11 to the changes you have noted on the 12 errata sheet, which will be attached to 13 your deposition. 14 It is imperative that you 15 return the original errata sheet to the 16 deposing attorney within thirty (30) days 17 of receipt of the deposition transcript 18 by you. If you fail to do so, the 19 deposition transcript may be deemed to be 20 accurate and may be used in court. 21 22 23 24</p>
<p style="text-align: right;">Page 663</p> <p>1 2 CERTIFICATE 3 4 5 I HEREBY CERTIFY that the 6 witness was duly sworn by me and that the 7 deposition is a true record of the 8 testimony given by the witness. 9 10 It was requested before 11 completion of the deposition that the 12 witness, JOSHUA E. MUSCAT, Ph.D., have 13 the opportunity to read and sign the 14 deposition transcript. 15 16 _____ 17 MICHELLE L. GRAY, 18 A Registered Professional 19 Reporter, Certified Shorthand 20 Reporter, Certified Realtime 21 Reporter and Notary Public 22 Dated: September 27, 2018 23 24 (The foregoing certification of this transcript does not apply to any reproduction of the same by any means, unless under the direct control and/or supervision of the certifying reporter.)</p>	<p style="text-align: right;">Page 665</p> <p>1 - - - - - 2 E R R A T A 3 - - - - - 4 PAGE LINE CHANGE 5 _____ 6 REASON: _____ 7 _____ 8 REASON: _____ 9 _____ 10 REASON: _____ 11 _____ 12 REASON: _____ 13 _____ 14 REASON: _____ 15 _____ 16 REASON: _____ 17 _____ 18 REASON: _____ 19 _____ 20 REASON: _____ 21 _____ 22 REASON: _____ 23 _____ 24 REASON: _____</p>

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<p style="text-align: right;">Page 666</p> <p>1</p> <p>2       <b>ACKNOWLEDGMENT OF DEPONENT</b></p> <p>3</p> <p>4       I, _____, do</p> <p>5 hereby certify that I have read the</p> <p>6 foregoing pages, 1 - 667, and that the</p> <p>7 same is a correct transcription of the</p> <p>8 answers given by me to the questions</p> <p>9 therein propounded, except for the</p> <p>10 corrections or changes in form or</p> <p>11 substance, if any, noted in the attached</p> <p>12 Errata Sheet.</p> <p>13</p> <p>14</p> <p>15 _____</p> <p>16       <b>JOSHUA E. MUSCAT, Ph.D.</b>       <b>DATE</b></p> <p>17</p> <p>18</p> <p>19       Subscribed and sworn</p> <p>20       to before me this</p> <p>21       _____ day of _____, 20____.</p> <p>22       My commission expires: _____</p> <p>23 _____</p> <p>24       Notary Public</p>	
<p style="text-align: right;">Page 667</p> <p>1       <b>LAWYER'S NOTES</b></p> <p>2       <b>PAGE LINE</b></p> <p>3       _____</p> <p>4       _____</p> <p>5       _____</p> <p>6       _____</p> <p>7       _____</p> <p>8       _____</p> <p>9       _____</p> <p>10       _____</p> <p>11       _____</p> <p>12       _____</p> <p>13       _____</p> <p>14       _____</p> <p>15       _____</p> <p>16       _____</p> <p>17       _____</p> <p>18       _____</p> <p>19       _____</p> <p>20       _____</p> <p>21       _____</p> <p>22       _____</p> <p>23       _____</p> <p>24       _____</p>	

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<b>A</b>	240:20,22	<b>addition</b> 366:10	348:17	493:18,23
<b>abided</b> 236:3	327:7 450:2	573:7	<b>afternoon</b>	552:21 555:19
<b>able</b> 49:11 94:9	461:23 583:13	<b>additional</b> 81:3	427:22 570:4,5	605:22 607:15
333:5 336:15	602:13 664:20	189:20 212:18	<b>age</b> 477:6	627:11
469:24 489:10	<b>accurately</b>	221:19 256:20	<b>ago</b> 52:9 60:10	<b>AHF</b> 166:13
512:6	595:18	366:12 419:24	60:12 105:17	174:15
<b>absence</b> 589:2,4	<b>acknowledge</b>	523:20 655:12	296:7 385:14	<b>al</b> 134:10 136:9
589:10,12	206:17 208:17	661:12	<b>agree</b> 17:5,17	435:6 443:17
657:4	250:5 305:15	<b>additives</b> 379:10	84:8 133:15	446:6 447:4
<b>absolutely</b> 83:15	373:1 386:17	<b>address</b> 15:9	148:16 309:14	<b>Alabama</b> 5:4
119:7 123:22	402:13 644:11	245:23 508:14	333:19 334:13	<b>Alexandria</b> 2:10
124:2 205:14	<b>acknowledged</b>	513:17,22	335:2 339:22	<b>algorithm</b>
332:11 393:6	300:12	<b>addressed</b>	340:8,20 342:3	424:15
393:17,18,22	<b>acknowledges</b>	303:14 419:24	342:13,18	<b>alleged</b> 24:1
444:16 471:17	249:21 302:20	646:8	344:14 406:17	169:12 597:21
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# Exhibit 158



Robert Glenn

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UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & )  
JOHNSON TALCUM POWDER )  
PRODUCTS MARKETING )  
SALES PRACTICES AND ) MDL 16-2738  
PRODUCT LIABILITY ) (FLW)(LHG)  
LITIGATION )  
\_\_\_\_\_)  
THIS DOCUMENT )  
RELATES TO ALL CASES )

THURSDAY, OCTOBER 18, 2018

- - -

Videotaped deposition of Robert  
Glenn, held at the offices of Grimes Teich  
Anderson LLP, 535 College Street, Asheville,  
North Carolina, commencing at 8:44 a.m., on  
the above date, before Carrie A. Campbell,  
Registered Diplomate Reporter and Certified  
Realtime Reporter.

- - -

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Robert Glenn

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<p>1 22 Non-Asbestiform Talc Overview, IARC 255 Monograph 93 Observers Meeting, San 2 Juan, PR, January 12, 2006, Crowell &amp; Moring 3 4 23 E-mail(s), 291 IMERYYS 309615 - IMERYYS 309623 5 24 E-mail(s), 313 JNJ 000004461 - JNJ 000004463 6 7 25 E-mail(s), 319 IMERYYS 001719 - IMERYYS 001720 8 26 February 25, 2006 letter from Eric 325 Turner to Robert A. Baan, Ph.D., 9 C&amp;M-LUZ 00001562 - C&amp;M-LUZ 00001563 10 27 February 23, 1978 letter to Roger 337 Miller, JNJ 000246710 - JNJ 000246717 11 12 28 Minutes Talc Section Teleconference 342 Meeting, IMA-NA - IMA-Europe, 13 February 24, 2006, JNJ 000004466 - JNJ 000004468 14 15 29 Rio Tinto Minerals Memorandum - 347 February 15, 2006, IMERYYS 241536 - IMERYYS 241544 16 17 30 E-mail(s), 362 IMERYYS 005117 18 31 Rio Tinto Minerals July 20, 2006 369 letter to John Worgan, 19 LUZ001441 - LUZ001444 20 32 Overview of Potential New Projects 377 Examining the Talc/Ovarian Cancer 21 Relationship, Huncharek and Muscat, IMERYYS 272247 - IMERYYS 2722450 22 23 33 Perineal talcum use and ovarian 379 cancer risk: A meta-analytic evaluation of the dose-response 24 relationship, Muscat and Huncharek, IMERYYS 242353 - IMERYYS 242362 25</p>	<p>1 VIDEOGRAPHER: Good morning. 2 We are now on the record. 3 My name is Darnell Brown, and 4 I'm the videographer with Golkow 5 Litigation Services. 6 Today's date is October 18, 7 2018, and the time is 8:44 a.m. 8 This video deposition is being 9 held in Asheville, North Carolina, in 10 the matter of In Re: Talc for the 11 United States District Court for the 12 Northern District of New Jersey. 13 The deponent is Robert Glenn. 14 Counsel will be noted on the 15 stenographic record. 16 The court reporter is Carrie 17 Campbell, who will now swear in the 18 witness. 19 20 ROBERT GLENN, 21 of lawful age, having been first duly sworn 22 to tell the truth, the whole truth and 23 nothing but the truth, deposes and says on 24 behalf of the Plaintiffs, as follows: 25</p>

3 (Pages 6 to 9)



Robert Glenn

<p style="text-align: right;">Page 10</p> <p>1 VIDEOGRAPHER: Counsel on the 2 phone, could you state your 3 appearances, please? 4 MR. KOHRS: Nicholas Kohrs with 5 Lundy, Lundy, Soileau &amp; South. 6 VIDEOGRAPHER: Anyone else? 7 MR. BOWDEN: Wes Bowden for the 8 plaintiffs. 9 MR. TISI: Chris Tisi for the 10 plaintiffs. 11 MR. FERGUSON: Ken Ferguson for 12 Imerys. 13 MR. HEGARTY: Mark Hegarty for 14 the Johnson &amp; Johnson defendants. 15 MS. FREY: Sara Frey for 16 Imerys. 17 MR. DONATH: Jonathan Donath 18 for Imerys. 19 MR. BILLINGS-KANG: James 20 Billings-Kang for Personal Care 21 Products Council. 22 MR. DAVANT: Oh, Charles Davant 23 for the witness. 24 THE WITNESS: Robert Glenn, 25 deponent.</p>	<p style="text-align: right;">Page 12</p> <p>1 just want to step back and tell you some of 2 the ground we're going to be covering today. 3 A. All right. 4 Q. So you see that there's cameras 5 here, right? 6 A. Yes. 7 Q. And you understand that today 8 you're under oath, right? 9 A. Yes. 10 Q. And this is not your first time 11 being under oath? 12 A. No. 13 Q. Not your first time giving a 14 deposition? 15 A. No, it's not. 16 Q. So you understand that your 17 testimony today might be used in evidentiary 18 hearings, might be given to other experts to 19 consider your testimony. 20 Do you understand that? 21 A. Yes, I understand that. 22 Q. You understand that your 23 testimony today may be played before the 24 judge? 25 A. I understand that.</p>
<p style="text-align: right;">Page 11</p> <p>1 DIRECT EXAMINATION 2 QUESTIONS BY MR. BOWDEN: 3 Q. All right. Good morning, sir. 4 A. Good morning. 5 Q. Please state your name for the 6 record. 7 A. Robert Glenn. 8 Q. Mr. Glenn, it's good to see you 9 again. It's been a couple of years since we 10 last met, hasn't it? 11 A. I don't recall the last time, 12 but... 13 Q. Okay. This is your first depo 14 in the talcum powder litigation; is that 15 right? 16 A. That's correct. 17 Q. All right. And you understand 18 that you're here today in a litigation 19 involving women who have alleged that they've 20 developed ovarian cancer as a result of their 21 use of talcum powder products. 22 You understand that? 23 A. I understand that. 24 Q. All right. And before we jump 25 into who you are and the different topics, I</p>	<p style="text-align: right;">Page 13</p> <p>1 Q. And ultimately, your testimony 2 today may be played in front of juries. 3 You understand that? 4 A. I understand that. 5 Q. Okay. So I want to make 6 something very clear right off the bat. When 7 I say "talc" today, when I say "talc" during 8 your deposition, I want you to have an 9 understanding that I mean talcum powder 10 products. Everything that's in the bottle 11 that a woman buys at a store, Kmart, Sears, 12 wherever it might be, when I say "talc," I'm 13 talking about talcum powder products, 14 cosmetic talc, and everything that's in the 15 bottle. 16 Do you understand that? 17 A. Yes. 18 MR. BILLINGS-KANG: Objection, 19 form. 20 QUESTIONS BY MR. BOWDEN: 21 Q. Now, let me just reiterate some 22 basic ground rules here. 23 From time to time you may hear 24 an objection from the numerous defense 25 attorneys who are in this room with you</p>

4 (Pages 10 to 13)



Robert Glenn

<p style="text-align: right;">Page 14</p> <p>1 today. Just let them state their objection 2 fully, and unless your attorney tells you not 3 to answer a question, give a full answer. 4 And of course if I ask a 5 question, do me the courtesy of letting me 6 ask the full question. And I'll extend the 7 same courtesy to you, let you give your full 8 answer. Fair? 9 A. That's fair. 10 Q. Okay. 11 MR. BILLINGS-KANG: And, 12 Counsel, may we have an stipulation 13 that an objection by one is an 14 objection by all? 15 MR. BOWDEN: Absolutely. 16 QUESTIONS BY MR. BOWDEN: 17 Q. So today we're going to be 18 talking about a number of issues, primarily 19 dealing with your involvement with the law 20 firm of Crowell &amp; Moring. 21 And you began working there in 22 2004; is that correct? 23 A. That's correct, 2004. 24 Q. And then your employment, your 25 direct employment with Crowell &amp; Moring, that</p>	<p style="text-align: right;">Page 16</p> <p>1 MR. HEGARTY: Object to form. 2 THE WITNESS: Well, the 3 scientific debate goes further back 4 than 2010, of course. 5 QUESTIONS BY MR. BOWDEN: 6 Q. Sure. 7 And I think you might even say 8 2004, it went back before then as well? 9 A. Yes, it did. 10 Q. Okay. And I understand that. 11 We're going to touch on some of those issues, 12 but we're going to focus a lot of your 13 testimony on that 2004 to 2010 time period. 14 And that time period, that 15 encompasses the second NTP nomination of 16 talc, right? 17 A. Yes. 18 Q. It encompasses your direct 19 involvement with the publication of 20 scientific literature? 21 A. It was not my direct 22 involvement with publication of scientific 23 literature. 24 Q. Okay. We're going to get to 25 that.</p>
<p style="text-align: right;">Page 15</p> <p>1 ended in 2010? 2 A. I left the firm in 2010. They 3 still had me doing work for the firm for 4 another four or five years, and then we 5 severed our relationship as far as a business 6 transaction. 7 Q. Okay. And so if my 8 recollection is correct, you left in 2010 to 9 form Glenn Consulting Group; is that right? 10 A. That's correct, I did. 11 Q. In 2010 through the 2015 time 12 period when you said they severed all ties 13 with you, were you working on talcum powder 14 product litigation again? 15 A. No, I was not working on talcum 16 powder for Crowell or for anyone else to my 17 recollection. 18 Q. Okay. So we're going to talk a 19 little bit about the 2004 time period 20 through 2010, but to give the jury an idea of 21 the type of material we're going to cover, 22 that was an important time period in talc and 23 the scientific debate that was going on in 24 the medical and public arena; is that fair to 25 say?</p>	<p style="text-align: right;">Page 17</p> <p>1 A. Okay. 2 Q. In 2006, there was an IARC 3 proceeding as well, right? 4 A. That's correct. IARC working 5 group met in Lyon, France. 6 Q. Uh-huh. And after 2006, up and 7 through 2010 and '11, there were numerous 8 scientific articles that had been submitted 9 for peer review which you had involvement in, 10 correct? 11 A. I commissioned some of those. 12 The sponsor was our client -- 13 Q. Okay. 14 A. -- Luzenac. But -- and I had 15 review of those papers, but I was not an 16 author or did not have significant input to 17 those papers. 18 Q. You did not have significant 19 input into those papers? 20 A. Into the published papers, 21 the -- 22 Q. Okay. 23 A. -- manuscripts, submitted for 24 publication. 25 Q. Okay. So we're going to talk</p>

5 (Pages 14 to 17)



Robert Glenn

<p style="text-align: right;">Page 18</p> <p>1 about some of those issues in greater detail.  2 A. Uh-huh.  3 Q. But I just wanted to give the  4 jury an idea of where we're headed in today's  5 testimony.  6 All right?  7 A. Sure.  8 Q. Now, you have a master's in  9 public health, right?  10 A. That's correct.  11 Q. What track, if any, did you  12 take in school?  13 A. My master's degree is in  14 industrial hygiene and occupational health  15 from the University of Minnesota School of  16 Public Health.  17 Q. Okay. And so industrial  18 hygiene. Anything else that you had a minor  19 or anything else in terms of science?  20 A. No, not at the University of  21 Minnesota, no. It was strictly a public  22 health degree.  23 Q. Industrial -- okay. Industrial  24 hygiene.  25 You're not a geologist, right?</p>	<p style="text-align: right;">Page 20</p> <p>1 various groups, and that's how you picked  2 some of this up, right?  3 A. Between NIOSH -- that was one  4 of the ways. And then of course after I left  5 NIOSH, I continued to have interest in the  6 topic.  7 Q. Sure.  8 Not a gynecologist?  9 A. No.  10 Q. Not an oncologist?  11 A. No.  12 Q. Not an epidemiologist?  13 A. No.  14 Q. And while you worked for a law  15 firm --  16 A. My training did include  17 epidemiology at the University of Minnesota.  18 Q. Sure. At course level?  19 A. Yes, but my -- yes, but my  20 track was not epidemiology.  21 Q. You don't hold yourself out as  22 an epidemiologist?  23 A. No, I don't.  24 Q. Okay. And you're not an  25 attorney, right?</p>
<p style="text-align: right;">Page 19</p> <p>1 A. No, I'm not a geologist.  2 Q. You're not a mineralogist?  3 A. No, I have a working knowledge  4 of geology and mineralogy, but I'm not a --  5 trained in those fields.  6 Q. Okay. And that was  7 self-taught, basically, right?  8 A. Self-taught, attendance at  9 meetings, meeting and discussing subjects  10 with mineralogists and geologists, yes.  11 Q. Okay. But not through  12 experience, correct?  13 A. Well, I'm not sure I -- I would  14 consider it was experience. While at NIOSH,  15 I took on the role as the liaison to the  16 mining industry to organize labor into  17 government agencies involved in mine safety  18 and health, and I met fairly frequently with  19 some of the geologists, leading  20 mineralogists, related to the topic.  21 Q. Sure. And we'll get into some  22 more of those details.  23 But I think maybe you used the  24 term there you were a liaison, you were  25 coordinating communication between these</p>	<p style="text-align: right;">Page 21</p> <p>1 A. No, I'm not.  2 Q. You worked at a law firm as a  3 consulting scientist?  4 A. That's correct.  5 Q. You were a liaison in that  6 capacity as well, correct?  7 A. Well, I wasn't a liaison. I  8 interacted with the attorneys in litigation,  9 more or less, in litigation support.  10 Q. Now, we're in a fairly small  11 room here today, so bear with me if it takes  12 me a minute to get these documents out to  13 you, but --  14 A. I could step out if you want me  15 to.  16 Q. No, no, we'll be fine.  17 Just as a side note, it is  18 fairly small in here, it's fairly cramped.  19 If you get to the point where you need to  20 take a break, just let me know.  21 A. I will do that. Thank you.  22 (Glenn Exhibit 1 marked for  23 identification.)  24 QUESTIONS BY MR. BOWDEN:  25 Q. So I'm going to mark for this</p>

6 (Pages 18 to 21)



Robert Glenn

<p style="text-align: right;">Page 22</p> <p>1 deposition -- excuse me, Exhibit 1 to this 2 deposition the notice of deposition. 3 Have you had an opportunity to 4 review that? 5 A. Yes, I did review that. 6 Q. Okay. And did you have an 7 opportunity to review that notice of 8 deposition with your attorneys? 9 A. Yes, I did review it with 10 counsel. 11 (Glenn Exhibit 2 marked for 12 identification.) 13 QUESTIONS BY MR. BOWDEN: 14 Q. Now, I'm going to mark as 15 Exhibit Number 2 the response from your 16 attorney to the notice of deposition. 17 Have you read the response? 18 A. Yes, I have. 19 Q. Did you have input into its 20 content? 21 A. We discussed it. 22 Q. And stop right there and just 23 ask you: What law firm are you represented 24 by here today? 25 A. I'm represented by Williams &amp;</p>	<p style="text-align: right;">Page 24</p> <p>1 Q. Okay. So page 4 at the very 2 bottom of the screen, you see a footnote 3 there? And it says, "Mr. Glenn has never 4 been retained by or on behalf of the other 5 defendants in MDL number 2738." 6 Do you see that? 7 A. That's what it says. 8 Q. And let's just be very clear 9 for the jury. The only client that you 10 worked for through the law firm of Crowell &amp; 11 Moring was Imerys? 12 A. It was Luzenac America at that 13 time. 14 Q. Sure. 15 And I think it's important -- 16 because we're going to be talking about a 17 couple of different names here. 18 When I say "Imerys" today, I'm 19 talking about the client that exists today, 20 right? Crowell &amp; Moring still represents 21 them, true? 22 A. Not to my knowledge. Crowell &amp; 23 Moring, I don't think, represents Imerys in 24 any way. 25 Q. Okay. They don't represent</p>
<p style="text-align: right;">Page 23</p> <p>1 Connolly. 2 Q. Are they your personal 3 attorneys? 4 A. They're my personal attorney. 5 Q. Who's paying for them? 6 A. Crowell &amp; Moring is paying for 7 them. 8 Q. Are you being paid for your 9 time today by Crowell &amp; Moring as well? 10 A. No, I'm not being paid at all 11 for my appearance here. 12 Q. Transportation costs? 13 A. Nothing. 14 Q. Okay. So I want you to turn to 15 page 4 -- 16 MR. DONATH: Counsel, do you 17 have any other copies of Exhibit 2? 18 MR. BOWDEN: I thought I handed 19 them out. If I didn't... 20 QUESTIONS BY MR. BOWDEN: 21 Q. So page 4. And, sir, we've got 22 on the screen here, too, if it might be 23 easier to follow along, the document's 24 displayed for you. Okay. That's fine. 25 A. My eyes are not that good.</p>	<p style="text-align: right;">Page 25</p> <p>1 them anymore, anyway? 2 A. Again, I'm not with the firm 3 anymore. I don't have access to that 4 information. 5 Q. Okay. 6 A. It's my understanding that they 7 do not represent Imerys. 8 Q. Well, let me restate this. 9 While you were employed at 10 Crowell &amp; Moring, Imerys was the client that 11 you were engaged in providing consulting 12 services to, true? 13 A. Yes. 14 Q. Okay. And now for clarity, 15 Imerys is the current iteration of that 16 company, but it's been known by other names, 17 right? 18 A. Yes. 19 MR. DONATH: Objection to form. 20 THE WITNESS: And when working 21 for it, as I mentioned, it was Luzenac 22 America. 23 QUESTIONS BY MR. BOWDEN: 24 Q. Right. 25 It was Luzenac America, and</p>

7 (Pages 22 to 25)



Robert Glenn

<p style="text-align: right;">Page 26</p> <p>1 then it became Rio Tinto?</p> <p>2 A. Well, yes, Rio Tinto owned --</p> <p>3 was --</p> <p>4 MR. DONATH: Objection to form.</p> <p>5 THE WITNESS: Rio Tinto was a</p> <p>6 major company over Luzenac America as</p> <p>7 well.</p> <p>8 QUESTIONS BY MR. BOWDEN:</p> <p>9 Q. Okay.</p> <p>10 A. It was one of its mining</p> <p>11 entities.</p> <p>12 Q. And now it's Imerys?</p> <p>13 A. Now it's Imerys.</p> <p>14 Q. And in that Exhibit Number 2,</p> <p>15 your CV is attached, right?</p> <p>16 A. Yes. Yes, it is.</p> <p>17 Q. Glenn Consulting Group, where</p> <p>18 is that based out of?</p> <p>19 A. It's based out of Seabrook</p> <p>20 Island, South Carolina.</p> <p>21 Q. All right. And is that -- are</p> <p>22 you a sole proprietor?</p> <p>23 A. I'm a sole proprietor. I carry</p> <p>24 my dog to work, but she doesn't do anything</p> <p>25 useful.</p>	<p style="text-align: right;">Page 28</p> <p>1 Q. Those on behalf of industrial</p> <p>2 clients?</p> <p>3 A. They were on behalf of</p> <p>4 industrial clients, yes.</p> <p>5 Q. Has Crowell -- or excuse me.</p> <p>6 Has Glenn Consulting ever represented an</p> <p>7 individual or provided consulting services to</p> <p>8 an individual?</p> <p>9 MR. DAVANT: Objection to form.</p> <p>10 THE WITNESS: In what manner</p> <p>11 are you speaking?</p> <p>12 QUESTIONS BY MR. BOWDEN:</p> <p>13 Q. Well, the people who have hired</p> <p>14 you, the entities --</p> <p>15 A. Yeah.</p> <p>16 Q. -- have they exclusively been</p> <p>17 corporations?</p> <p>18 A. Yes, they have.</p> <p>19 Q. Exclusively been corporations</p> <p>20 in the mining industry?</p> <p>21 A. Not necessarily. No, not --</p> <p>22 not all of them have been in the mining</p> <p>23 industry.</p> <p>24 Q. Right.</p> <p>25 Some of them have been in other</p>
<p style="text-align: right;">Page 27</p> <p>1 Q. And it was formed in 2010,</p> <p>2 right?</p> <p>3 A. Yes.</p> <p>4 Q. And that was formed upon you</p> <p>5 being -- leaving Crowell &amp; Moring, correct?</p> <p>6 A. Correct.</p> <p>7 Q. And prior to 2010, the 2004 to</p> <p>8 2010 time period, your sole employer, would</p> <p>9 that have been Crowell &amp; Moring?</p> <p>10 A. Yes, it was.</p> <p>11 Q. Okay. You didn't work for</p> <p>12 anybody else during that time period?</p> <p>13 A. No.</p> <p>14 Q. Between 2010 and 2015, where</p> <p>15 did Glenn consulting derive the majority of</p> <p>16 its income?</p> <p>17 A. Mainly from research in</p> <p>18 silicosis studies. There were three major</p> <p>19 studies I was working on with colleagues from</p> <p>20 academia.</p> <p>21 Q. You were actually an author on</p> <p>22 one of those studies, weren't you?</p> <p>23 A. I was author on -- yes, on one</p> <p>24 of those studies. The other two are still in</p> <p>25 progress.</p>	<p style="text-align: right;">Page 29</p> <p>1 industrial settings, true?</p> <p>2 A. Uh-huh.</p> <p>3 Q. Companies like DuPont?</p> <p>4 A. Yes. Yes.</p> <p>5 Q. How do you advertise your</p> <p>6 services, or how did you in that 2010 to 2015</p> <p>7 time period?</p> <p>8 A. I haven't advertised my</p> <p>9 services. My work has come by knowing people</p> <p>10 that know of my background and my experience.</p> <p>11 Q. Just word of mouth?</p> <p>12 A. Yes. I had a LinkedIn page,</p> <p>13 but I don't have a website. I have a domain</p> <p>14 name, but I never put up a website.</p> <p>15 Q. How many -- sorry.</p> <p>16 Between 2010 and 2015, aside</p> <p>17 from DuPont, what other companies did you</p> <p>18 consult with?</p> <p>19 MR. DAVANT: Just to caution</p> <p>20 the witness, if you would have to</p> <p>21 reveal information that's protected by</p> <p>22 client confidentiality, you shouldn't</p> <p>23 do that.</p> <p>24 THE WITNESS: Would the company</p> <p>25 names be that or...</p>

8 (Pages 26 to 29)



Robert Glenn

<p style="text-align: right;">Page 30</p> <p>1 MR. DAVANT: Yeah, it could be.  2 THE WITNESS: Okay. I have  3 a -- probably in that period have had  4 18 to 20 clients.  5 QUESTIONS BY MR. BOWDEN:  6 Q. Different clients?  7 A. On -- yes, probably that many.  8 On the research end, I was -- I  9 did some work for the National Industrial  10 Sand Association, National Stone, Sand and  11 Gravel Association and Vulcan Materials.  12 Q. What companies did you provide  13 consulting work for that you aren't  14 underneath a confidentiality agreement in  15 terms of the name?  16 A. That goes back. Pfizer.  17 Q. And Pfizer is a drug company,  18 right?  19 A. Yes, a pharmaceutical  20 manufacturer.  21 Q. They create pharmaceutical  22 products, right?  23 A. Correct.  24 Q. Do they own some liability for  25 asbestos manufacturers?</p>	<p style="text-align: right;">Page 32</p> <p>1 Q. Okay. And DuPont, that was  2 also in regards to cancer, correct?  3 A. It was involved related to a  4 lot of potential disease outcomes, cancer  5 being one.  6 Q. One of which was cancer?  7 A. Yes.  8 Q. All right. And then you said  9 Lafarge?  10 A. Yes.  11 Q. Can you describe that company  12 for us?  13 A. Describe the company?  14 Q. Yeah.  15 What was the nature of your  16 consulting services?  17 A. It was litigation related to  18 asbestos.  19 Q. Okay. What other companies?  20 A. There was Southern Talc.  21 Q. I'm assuming the name implies  22 that it was a talc company, correct?  23 A. Yes.  24 Q. Was it also in regards to  25 cancer?</p>
<p style="text-align: right;">Page 31</p> <p>1 A. Not asbestos that I'm aware of.  2 Q. Silica?  3 A. I don't think they're in any  4 litigation related to silica either.  5 Q. Okay. What was the nature of  6 the consulting work that you did for them,  7 what topics?  8 A. Talc.  9 Q. What other manufacturers?  10 A. Of course, you mentioned  11 DuPont.  12 Q. And DuPont, that was dealing  13 with a water contamination issue, correct?  14 A. Yes. Yes. I did work for  15 Lafarge.  16 Q. Now, I want to pause real quick  17 and go back.  18 Pfizer talc, was that in  19 regards to ovarian cancer as well?  20 A. No, it was not.  21 MR. HEGARTY: Objection, form.  22 QUESTIONS BY MR. BOWDEN:  23 Q. Was it involved in cancer  24 research?  25 A. Yes.</p>	<p style="text-align: right;">Page 33</p> <p>1 MR. HEGARTY: Objection, form.  2 MR. DONATH: Form.  3 THE WITNESS: Yes.  4 QUESTIONS BY MR. BOWDEN:  5 Q. What other companies?  6 A. You're stretching my memory.  7 Those are the ones that stand out right away,  8 but there are others.  9 Q. Would it be fair to say that  10 your consulting services between 2010 and  11 2015 were largely dealing with talc and with  12 asbestos matters?  13 MR. DONATH: Objection. Form.  14 THE WITNESS: On that side of  15 consulting, yes. On the research it  16 was silica.  17 QUESTIONS BY MR. BOWDEN:  18 Q. Sure.  19 A. And the research studies were  20 quite large studies. They were all near  21 million dollars in cost. Significant  22 studies.  23 Q. Why do you point out the  24 expense of the...  25 A. Just to give you an</p>



Robert Glenn

<p style="text-align: right;">Page 34</p> <p>1 appreciation for how much involvement I had 2 in those. It took quite a bit of my time. 3 Q. Okay. So when you say a 4 million dollars, is that a million dollars to 5 you? 6 A. No, but that -- not quite that, 7 no. 8 Q. So you're talking about the 9 studies themselves, right? 10 A. Yes. Yes. 11 Q. And the funding that went into 12 those? 13 A. The investigators, the research 14 cost, the data collection, data analysis, the 15 whole kit and caboodle. 16 Q. Sure, because research can be 17 expensive, especially the more detailed of 18 analysis that goes into it, right? 19 A. It can be, yes. 20 Q. Did you discuss today's 21 deposition with anyone other than your 22 counsel? 23 A. No. 24 Q. How much time did you spend 25 preparing for today's deposition?</p>	<p style="text-align: right;">Page 36</p> <p>1 the attorney selected for you? 2 A. That the attorney provided me, 3 yes. 4 Q. Are there any documents you 5 didn't see that you wanted to see? 6 A. No. 7 Q. Now, you've mentioned NIOSH a 8 few times. 9 Explain to the jury what NIOSH 10 is. 11 A. NIOSH is the National Institute 12 for Occupational Safety and Health. It 13 was -- came about in 1970 legislation which 14 formed the Occupational Safety and Health 15 Administration and the National Institute for 16 Occupational Safety and Health. 17 OSHA is in the Department of 18 Labor. It's an enforcement agency that 19 enforces health and safety regulations in 20 general industry and in industry outside of 21 mining. 22 NIOSH is a research arm. At 23 the time, it was in the Department of Health 24 and Education and Welfare. It's now in the 25 Department of Health and Human Services. And</p>
<p style="text-align: right;">Page 35</p> <p>1 A. Maybe three days. 2 Q. Were you paid for that time? 3 A. No. 4 Q. What materials did you review 5 during those three days? 6 A. Counsel provided a list of 7 documents, a couple of volumes of documents, 8 that had been -- been in discovery, have been 9 obtained, and I went through many -- most of 10 those, all of those. 11 Q. Which attorney provided them? 12 A. Counsel to -- Williams 13 Connolly. 14 Q. The attorneys hired by 15 Crowell &amp; Moring to represent you? 16 A. That's correct. 17 Q. Okay. 18 A. Mr. Davant. 19 Q. And in reading those documents, 20 did you ask for any additional documents? 21 A. No, I did not. 22 Q. So you only read for 23 preparation -- excuse me -- strike that. 24 In preparing for today's 25 deposition, you reviewed the documents that</p>	<p style="text-align: right;">Page 37</p> <p>1 they were essentially formed to do research 2 in occupational health and safety and provide 3 recommendations to Department of Labor. 4 There's another organization in 5 the Department of Labor, the Mine Safety and 6 Health Administration, which regulates -- 7 regulates the mining industry in safety and 8 health. It came about in 1977. 9 Q. One of their overall missions 10 is to look out for workers and protect human 11 health; fair to say? 12 A. Yes, it's to develop research 13 to protect the health of workers, health and 14 safety of workers. 15 Q. And you would agree with me 16 that research develops over time, right? 17 A. Yes, it does. 18 Q. Science progresses as more and 19 more data is collected, true? 20 A. Certainly. 21 Q. Okay. And at some point you 22 actually rise to the director level in NIOSH? 23 A. Yes, I was director. 24 Q. And as director, did you oppose 25 NIOSH's expansion of the definition of</p>

10 (Pages 34 to 37)



Robert Glenn

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<p>1 asbestos?</p> <p>2 A. I didn't -- I never published a</p> <p>3 policy -- anything opposing the NIOSH policy.</p> <p>4 I was not in agreement with their definition</p> <p>5 of asbestos, as well as other scientists in</p> <p>6 my division, the scientists in academia. We</p> <p>7 all felt that they had an improper definition</p> <p>8 of asbestos.</p> <p>9 Q. We can agree today that</p> <p>10 asbestos is a carcinogen, right?</p> <p>11 MR. DAVANT: Objection to form.</p> <p>12 THE WITNESS: Asbestos in</p> <p>13 asbestiform minerals is a carcinogen.</p> <p>14 QUESTIONS BY MR. BOWDEN:</p> <p>15 Q. So we can agree that asbestos</p> <p>16 is a carcinogen?</p> <p>17 A. When you say as --</p> <p>18 MR. DAVANT: Same objection.</p> <p>19 THE WITNESS: When you say</p> <p>20 asbestos, I like to use a qualifier,</p> <p>21 and that is, it's asbestiform -- it's</p> <p>22 from an asbestiform habit.</p> <p>23 QUESTIONS BY MR. BOWDEN:</p> <p>24 Q. Is it fair to say that asbestos</p> <p>25 fiber is a carcinogen?</p>	<p>1 good.</p> <p>2 Q. It says, "The testimony</p> <p>3 restated the definition currently in place at</p> <p>4 NIOSH for asbestos. Concern had arisen</p> <p>5 following the issuance of an internal</p> <p>6 memorandum by Mr. Robert Glenn, who was the</p> <p>7 director of the division of respiratory</p> <p>8 disease studies at NIOSH. This memorandum</p> <p>9 did not change the position of NIOSH</p> <p>10 concerning the definition of asbestos as it</p> <p>11 concerns regulatory purposes."</p> <p>12 Do you see where it says that?</p> <p>13 A. Yes. Yes.</p> <p>14 Q. And so you were actually</p> <p>15 criticized for your internal memorandum</p> <p>16 opposing the definition of asbestos, correct?</p> <p>17 MR. DONATH: Objection to form.</p> <p>18 MR. HEGARTY: Objection.</p> <p>19 THE WITNESS: You're correct,</p> <p>20 that was an internal memorandum. It</p> <p>21 was NIOSH that released it under the</p> <p>22 Freedom of Information Act.</p> <p>23 QUESTIONS BY MR. BOWDEN:</p> <p>24 Q. Right. It was internal, wasn't</p> <p>25 meant for the public eyes.</p>
Page 39	Page 41
<p>1 MR. HEGARTY: Objection to</p> <p>2 form.</p> <p>3 THE WITNESS: Not necessarily</p> <p>4 fiber. An asbestiform fiber is a</p> <p>5 carcinogen.</p> <p>6 QUESTIONS BY MR. BOWDEN:</p> <p>7 Q. Okay.</p> <p>8 A. Fiber -- not all fibrous</p> <p>9 minerals are asbestos, and not all...</p> <p>10 (Glenn Exhibit 3 marked for</p> <p>11 identification.)</p> <p>12 QUESTIONS BY MR. BOWDEN:</p> <p>13 Q. I'm going to mark as Exhibit</p> <p>14 Number 3, it's a web page printout from the</p> <p>15 CDC.</p> <p>16 I want you to read along with</p> <p>17 me where it says "abstract."</p> <p>18 A. Let me just look at it and</p> <p>19 get -- for a second.</p> <p>20 Q. Sure. And I'm going to show</p> <p>21 you the whole document.</p> <p>22 A. Okay.</p> <p>23 Q. Go ahead and read it, if you'd</p> <p>24 like.</p> <p>25 A. Okay. I've -- all right. It's</p>	<p>1 A. It didn't have to be released</p> <p>2 under the Freedom of Information Act.</p> <p>3 Q. Okay.</p> <p>4 A. This was predecisional to the</p> <p>5 standard.</p> <p>6 Q. Does that disturb you, that it</p> <p>7 became public knowledge?</p> <p>8 MR. DONATH: Objection to form.</p> <p>9 THE WITNESS: Yes. I was</p> <p>10 trying to keep it internal.</p> <p>11 If you read the memo, it goes</p> <p>12 to the point that my communication</p> <p>13 was --</p> <p>14 QUESTIONS BY MR. BOWDEN:</p> <p>15 Q. Sir, my question was simply --</p> <p>16 A. I'm sorry, you said you</p> <p>17 wouldn't interrupt me.</p> <p>18 MR. DONATH: Let him get his</p> <p>19 whole answer out.</p> <p>20 QUESTIONS BY MR. BOWDEN:</p> <p>21 Q. I want you to answer the</p> <p>22 question that I asked.</p> <p>23 A. I am. I am.</p> <p>24 Q. I'm going to move to strike it.</p> <p>25 A. All right.</p>

11 (Pages 38 to 41)



Robert Glenn

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<p>1 My memo is to Dr. Lemon, who 2 was director of DSDTT. He was aware of my 3 concerns about the definition, and I was 4 recommending to him that we have a 5 scientific -- convene scientific -- 6 scientific meeting of NIOSH scientists to 7 discuss this issue and go forward. 8 Q. And, Corey, will you show -- 9 this was fiscal year 1986, right? 10 A. That's correct. 11 Q. Okay. And after that, you left 12 NIOSH and you went to work for something 13 called the National Industrial Sand 14 Association? 15 A. That's right. 16 Q. And that's an industry front 17 group, right? 18 MR. DONATH: Objection to form. 19 MR. HEGARTY: Objection to 20 form. 21 THE WITNESS: It's not a front 22 group. It's a trade association 23 that -- 24 QUESTIONS BY MR. BOWDEN: 25 Q. Okay.</p>	<p>1 industry through development of a model, 2 silicosis prevention program that was 3 essentially lifted and put into the current 4 OSHA standard for silica. 5 (Glenn Exhibit 4 marked for 6 identification.) 7 QUESTIONS BY MR. BOWDEN: 8 Q. I'll mark as Exhibit Number 4 9 the National Industrial Sand Association web 10 page. 11 Have you visited it recently? 12 A. No, I have not. 13 Q. I'm going to turn to page 2 of 14 3. 15 A. Okay. 16 MR. DONATH: Objection. 17 Counsel, the document you've handed 18 out as Exhibit 4 is dated 2018. 19 Is that the correct date that 20 you meant for this printout? 21 QUESTIONS BY MR. BOWDEN: 22 Q. Are you on page 2, sir? 23 A. Yeah. 24 Q. Okay. I want you to look down 25 where it says "the .1-milligram-per-meter-</p>
Page 43	Page 45
<p>1 A. -- represents companies that 2 mine and process industrial sand. 3 Q. I see. 4 So it's -- it's an industry 5 group, a trade organization? 6 A. It's a trade organization. 7 Q. That represents the interests 8 of silica sand manufacturers? 9 A. Yes, it does. 10 Q. Gravel manufacturers? 11 A. No, not gravel. 12 Q. Okay. You're dealing with 13 silicates, though, in that, true? 14 A. We're dealing with crystalline 15 silica in a near pure form. 16 Q. And you were vice president 17 there, and then you became the CEO from '92 18 to 2004, right? 19 A. That's correct. 20 Q. And the number one advocacy 21 points for NISA, do you know what it is? 22 A. The number one? 23 Q. Advocacy point, yes, sir. 24 A. Yeah, it's -- it's protecting 25 workers' health in the industrial sand</p>	<p>1 cubed PEL is protective." 2 Do you see that? 3 MR. DONATH: Objection. Beyond 4 the scope. 5 THE WITNESS: Yes, I do see 6 that. 7 QUESTIONS BY MR. BOWDEN: 8 Q. And it has always been this 9 organization's purpose to oppose regulations 10 which would make it more restrictive in terms 11 of silica dust, correct? 12 MR. DONATH: Objection. Beyond 13 the scope. 14 THE WITNESS: No. No it was 15 not. 16 QUESTIONS BY MR. BOWDEN: 17 Q. Okay. And -- 18 A. This -- I mentioned the funding 19 of research -- 20 Q. Sir, there's no question 21 pending right now. 22 MR. DAVANT: You keep 23 interrupting the witness. 24 MR. BOWDEN: No, I don't. I'm 25 asking an examination. If you want to</p>

12 (Pages 42 to 45)



Robert Glenn

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<p>1 have questions for him on follow-up, 2 I'll give you the opportunity. 3 THE WITNESS: I want to tell 4 you about -- 5 MR. BOWDEN: No, sir, you're 6 not. You're going to answer -- 7 THE WITNESS: All right. This 8 organization funded -- 9 MR. BOWDEN: There's no 10 question pending. 11 THE WITNESS: -- a major 12 research study that cost over \$750,000 13 to look at the relationship between 14 crystalline silica exposure and lung 15 cancer and other disease end points as 16 well. 17 I was the one that wanted to -- 18 I was the one that wanted to sponsor 19 that study. I have my bias. I 20 thought it would be a negative study. 21 Everyone has bias. When you do 22 a study, you put aside that bias. 23 As it turned out, that study 24 conducted by Drs. Corb and McDonald -- 25 Allison McDonald, Dr. Hans Weil, Janet</p>	<p>1 regulations that recognize silicosis is 2 preventable through a series of simple and 3 effective occupational health measures; 4 however, we oppose the lowering of the PEL 5 because it has been proven protective." 6 MR. DONATH: Objection. Beyond 7 the scope. 8 THE WITNESS: For silicosis, 9 that was the understanding. That's 10 what NISA put forward at that time. I 11 was no longer with NISA, but I agree 12 with that. 13 You didn't call attention to 14 page 1 -- 15 QUESTIONS BY MR. BOWDEN: 16 Q. Sir, I'm -- 17 A. -- where there's a paragraph on 18 silicosis -- 19 Q. I'm sorry, sir, there is no 20 question pending. 21 A. -- and how to prevent 22 silicosis. 23 Q. This is not an opportunity for 24 you to just go on a soapbox. You have an 25 opportunity when your counsel asks you</p>
Page 47	Page 49
<p>1 Hughes and Roy Rando came out to be a 2 positive study. It showed the 3 relationship between crystalline 4 silica and lung cancer, so it 5 supported OSHA's reduction of the 6 standard. 7 Furthermore, we just completed 8 another study and submitted two 9 papers, and this is on silica and 10 silicosis, radiographic silicosis. 11 Those studies as well I thought would 12 be negative; they were positive. And 13 they then, too, add support to OSHA's 14 reduction in the crystalline silica 15 PEL. 16 So I'm a public health 17 professional, and that's my job, to 18 protect workers. And that's what I 19 was doing, and that's what this 20 organization was doing. 21 QUESTIONS BY MR. BOWDEN: 22 Q. So if you look underneath where 23 it -- we got it pulled up here on the screen 24 for you. 25 "We support reasonable</p>	<p>1 questions to answer their questions. 2 MR. DONATH: Objection. Move 3 to strike the comment by -- 4 THE WITNESS: You're not my 5 counsel. 6 MR. DONATH: And frankly, 7 Counsel, you can't predict the future, 8 and you don't know where the witness 9 is going with his answer. So if he 10 keeps talking, I would assume that's 11 part of his answer as well. 12 THE WITNESS: And I plan to put 13 my -- 14 MR. BOWDEN: You need to limit 15 your objections to form. 16 THE WITNESS: I plan to answer 17 with my context. 18 QUESTIONS BY MR. BOWDEN: 19 Q. From this trade organization, 20 you moved on to the industrial mining 21 association of North America, right? 22 A. No, we formed the industrial 23 mining association North America in 2002, and 24 NISA was a part of that organization. 25 Q. Right.</p>

13 (Pages 46 to 49)



Robert Glenn

<p style="text-align: right;">Page 50</p> <p>1 And you credit yourself on your 2 LinkedIn page with being one of the founders, 3 or the founder, of that organization, right? 4 A. No. I've said, "along with 5 industry leaders, I was a founder of this 6 organization." 7 Q. So let me make sure I 8 understand then. 9 It was Bob Glenn, you 10 individually, along with industry leaders. 11 Would that be the industry itself? 12 A. That would be the industry 13 leaders of the mineral commodities that this 14 organization formed to represent. 15 Q. I see. 16 (Glenn Exhibit 5 marked for 17 identification.) 18 QUESTIONS BY MR. BOWDEN: 19 Q. I'm going to mark as Exhibit 20 Number 5 the IMA web page listing their 21 purpose and description. 22 MR. BOWDEN: Corey, if you'll 23 bring up the whole body there. Yes, 24 sir. 25 QUESTIONS BY MR. BOWDEN:</p>	<p style="text-align: right;">Page 52</p> <p>1 ball clay, bentonite, borates, calcium 2 carbonate, feldspar, industrial sand -- 3 That would include silica sand, 4 right? 5 A. Yes. 6 Q. -- mica, soda ash, talc -- 7 A. Yes. 8 Q. -- and wollastonite, right? 9 A. Yes. 10 Q. In talc, you actually have 11 several members that -- of the IMA-North 12 America when you were there that were talc 13 producers, right, miners? 14 A. Yes, I'm not sure -- they may 15 have added companies and probably have added 16 talc companies since I left in 2004. 17 Q. Right. And I'm going to ask 18 you some questions about that. 19 A. Okay. Good. 20 Q. When you formed this 21 organization in 2002, was Imerys a cofounder? 22 A. I don't -- I think they were. 23 I'm not sure. I would have to see documents 24 related to that. 25 Q. Were other talc manufacturers</p>
<p style="text-align: right;">Page 51</p> <p>1 Q. Can you read long with me at 2 the top here? "The Industrial Minerals 3 Association - North America is a trade 4 organization created to advance the interests 5 of North American companies that mine or 6 process minerals used throughout the 7 manufacturing and agricultural industries." 8 Have I read that correctly? 9 A. Yes. 10 MR. DONATH: Objection. Same 11 objection. Beyond the scope. It's a 12 2018 document. 13 QUESTIONS BY MR. BOWDEN: 14 Q. Was that the same purpose that 15 it had when you formed it in 2002? 16 A. It may have been, yes. You 17 know, I didn't prepare this or the website, 18 but that might have been in a document 19 somewhere. 20 Q. Do you disagree with that 21 mission statement, sir? 22 A. No, we weren't advancing 23 interests in mineral companies. 24 Q. Examples of minerals 25 represented by the IMA-North America include</p>	<p style="text-align: right;">Page 53</p> <p>1 cofounders as well? 2 A. Well, I'm not sure -- 3 MR. DONATH: Objection to form. 4 THE WITNESS: I'm not sure 5 Imerys was, but I would have to, you 6 know, see something. 7 I do remember IMI Fabi and 8 RT Vanderbilt were members. 9 QUESTIONS BY MR. BOWDEN: 10 Q. Okay. Did they help provide -- 11 A. It may have been more. 12 Q. Sorry, I didn't mean to 13 interrupt you. 14 A. That's all right. 15 Talc manufacturers provided the 16 funding to get this organization off the 17 ground. 18 MR. DONATH: Objection to form. 19 THE WITNESS: They were one 20 that -- actually, NISA -- 21 MR. HEGARTY: Objection to 22 form. 23 THE WITNESS: -- was a big 24 underwriter of this whole adventure, 25 or venture, for the first few years,</p>

14 (Pages 50 to 53)



Robert Glenn

Page 54	Page 56
<p>1 and NISA was paying the lion's share 2 of the expenses for the IMA-NA. 3 QUESTIONS BY MR. BOWDEN: 4 Q. Did NISA have talc 5 manufacturers as members? 6 A. No. 7 Q. Interesting. 8 So NISA was a big proponent of 9 this, to bring talc manufacturers into the 10 trade organization? 11 MR. DONATH: Objection. Form. 12 THE WITNESS: Some of the -- 13 some of the NISA companies were 14 horizontally integrated into other 15 minerals, so that was their interest 16 in getting a group together. 17 This organization was modeled 18 after the Industrial Minerals 19 Association - Europe. 20 QUESTIONS BY MR. BOWDEN: 21 Q. Right. 22 A. And so we kind of took their -- 23 their game plan and introduced it here in the 24 United States and North America since we have 25 Canadian members.</p>	<p>1 especially for their EUROSIL industry. 2 Q. So now you were the president 3 of NISA at the time, right? 4 A. That's correct. 5 Q. And you said that it was NISA 6 who provided the funding to get IMA-North 7 America off the ground -- 8 A. The bulk -- 9 Q. The lion's share, I think is 10 what you said. 11 A. The bulk, yeah, that's correct. 12 Q. Let me restate that. 13 When you were president of 14 NISA, you had a meeting with IMA-Europe, 15 true? 16 A. Uh-huh, yes. 17 Q. When you were president of 18 NISA, was it your decision and direction that 19 funds be used to help get IMA-North America 20 off the ground? 21 MR. DONATH: Objection to form. 22 THE WITNESS: No, the board, 23 the NISA board, made that decision. 24 QUESTIONS BY MR. BOWDEN: 25 Q. Was it your recommendation?</p>
Page 55	Page 57
<p>1 Q. And I'm sorry, you trailed off 2 a little bit there. And Canadian members? 3 Was that what you said? 4 A. Yes, we have Canadian members. 5 Q. Okay. 6 A. Or had Canadian. And they 7 still have Canadian members. It's probably 8 added some. It's grown since I left there, 9 of course. 10 Q. Sure. 11 And it grew while you were 12 there as well, right? 13 A. Well, we -- actually, from the 14 time we formed, I don't know if we added any 15 members in the two years that I was still 16 with the organization. 17 Q. Okay. So let me ask you: 18 IMA-Europe, did you have involvement with 19 IMA-Europe before 2002? 20 A. Before 2002, I may have. 21 Q. In what capacity? 22 A. I believe I attended one of 23 their meetings to discuss the silicosis 24 prevention program, the model program, that 25 we had put together for their industry and</p>	<p>1 A. No, it was not. 2 Well, yes, in a way it was my 3 recommendation, but they had the final 4 decision, of course. 5 Q. Sure. 6 A. It was their funds. 7 Q. And at that time, NISA did not 8 represent the interests of talc 9 manufacturers, true? 10 A. They did not. I might -- 11 Q. But the formation of IMA-North 12 America from day one, as it was founded, 13 would have multiple talc manufacturers 14 involved? 15 A. I'm not sure how many. There 16 were some, yes. 17 Q. More than one, right? 18 A. Yes. 19 Q. Okay. 20 MR. BOWDEN: Corey, can we go 21 back to that page? 22 Pull up the second paragraph. 23 You can make that bigger. 24 I can read it the way it is. 25 Just go back to the full.</p>

15 (Pages 54 to 57)



Robert Glenn

Page 58	Page 60
<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. "The IMA-North America is open 3 to membership of industrial mineral producers 4 and companies that provide equipment and 5 services to the industry." 6 Do you see where that's 7 written, sir? 8 A. Yes. 9 MR. DONATH: Objection. Form. 10 Excuse me, withdrawn. 11 QUESTIONS BY MR. BOWDEN: 12 Q. "IMA-North America operates 13 through a board of directors augmented by 14 standing committees and task force." 15 Do you see that there? 16 A. Yes. 17 Q. "Through its committee 18 structure, IMA addresses such issues as 19 safety and health, government affairs, the 20 environment, industry operations, engineering 21 and technology, research and transportation." 22 MR. DONATH: Objection. Beyond 23 the scope. 24 QUESTIONS BY MR. BOWDEN: 25 Q. Correct.</p>	<p>1 please? 2 QUESTIONS BY MR. BOWDEN: 3 Q. I'm going to mark as Exhibit 4 Number 6 another web page from the IMA 5 website called Producer Members. 6 A. Yes. 7 Q. And I apologize, the font's 8 kind of small to read. We're trying to make 9 it larger. 10 Now, I want to turn to page 2, 11 the top of page 2. 12 A. Yes. 13 MR. DONATH: Counsel, do you 14 have another copy of your Exhibit 6? 15 MR. BOWDEN: Yes, sir, I've got 16 an extra copy. 17 MR. DONATH: Thank you. 18 QUESTIONS BY MR. BOWDEN: 19 Q. Do you see Imerys is listed at 20 the top there, right? 21 MR. DONATH: Objection. Beyond 22 the scope. It's another 2018 23 document. 24 THE WITNESS: Yes. 25</p>
Page 59	Page 61
<p>1 A. And I would note that the 2 issues of safety and health are number one in 3 that list. 4 Q. Did I read it correctly? 5 A. Yes. 6 Q. And in there is research, 7 right? 8 A. Yes. 9 Q. And IMA-North America actually 10 sponsors research on behalf of its members, 11 true? 12 A. I'm not -- IMA did not -- well, 13 they sponsor some research on technology for 14 the industry. I'm not sure they sponsored 15 any safety and health research at the time I 16 was there. I don't think IMA-NA did. 17 Q. Okay. As a general point, 18 though, the IMA-North America does found 19 research? 20 A. Yes. 21 MR. DONATH: Objection. Form. 22 (Glenn Exhibit 6 marked for 23 identification.) 24 MR. BOWDEN: Corey, can you 25 pull up producer members for me,</p>	<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. And while you were at IMA-North 3 America, Imerys was a member, true? 4 MR. DONATH: Objection. Form. 5 THE WITNESS: I'm not sure. I 6 know we -- we paid a visit to calcium 7 carbonate company in Georgia, and I 8 don't know whether at that time it was 9 a separate company and Imerys acquired 10 it later. I'm just vague on that. 11 But in the period when we were trying 12 to build membership, we did visit a 13 corporation, a calcium carbonate 14 corporation, to try to and get them to 15 join. 16 QUESTIONS BY MR. BOWDEN: 17 Q. What about Luzenac when you 18 were there? 19 MR. DONATH: Objection. Form. 20 THE WITNESS: I'm not sure when 21 the Luzenac came, but they may have 22 been an initial member. But it's 23 stated, this is a 2018 document. 24 QUESTIONS BY MR. BOWDEN: 25 Q. Right, I'm not saying that this</p>

16 (Pages 58 to 61)



Robert Glenn

<p style="text-align: right;">Page 62</p> <p>1 says the day that they joined.  2 I'm asking you as the president  3 and founder of this whether you recall them  4 being members at the time you were there.  5 A. I did not recall them. Let me  6 take a look, and I might can tell you.  7 Q. I'll represent to you that it  8 doesn't have on here their join date.  9 A. Okay. Right. Okay.  10 Q. And I wasn't able to find that  11 information, but I'm interested in knowing as  12 you, Bob Glenn, the person who founded this  13 and was the president and CEO of IMA-North  14 America, whether in that capacity you had  15 dealings with Imerys or Luzenac while you  16 were the president and CEO of IMA-North  17 America.  18 MR. DONATH: Objection, form.  19 THE WITNESS: I may have.  20 Again, this was some years ago. Yeah,  21 I remember IMI Fabi and Specialty  22 Minerals.  23 I don't know when exactly  24 Luzenac became a member -- or Imerys  25 became a member of the talc section.</p>	<p style="text-align: right;">Page 64</p> <p>1 right?  2 A. Yeah.  3 Q. They're the mining company?  4 A. The mining process minerals,  5 correct.  6 Q. Okay. And associate members  7 are people who are also members of the  8 organization, right?  9 A. They are vendors and service  10 companies, consultants and such, that belong  11 to the association. I don't believe  12 associate members have a right to vote.  13 Q. Okay. But they have a right to  14 participate in meetings?  15 A. Yes.  16 Q. They have a right to  17 participate in presentations?  18 A. Yes.  19 Q. They have a right to  20 participate when there are meetings between  21 different trade organizations involving  22 IMA-North America, true?  23 A. I don't know if -- well, they  24 can sit in on some meetings, yes.  25 Essentially if they wanted to sit in the</p>
<p style="text-align: right;">Page 63</p> <p>1 I'm now looking at the talc  2 section, and Specialty Minerals was a  3 original member, Vanderbilt, IMI Fabi,  4 which I mentioned before. I just -- I  5 can't really recall about Imerys.  6 QUESTIONS BY MR. BOWDEN:  7 Q. Okay. Fair enough. We're  8 going to put that one aside.  9 A. But Mr. Ellis, the current  10 president, could probably find that out from  11 his files.  12 Q. Right. He's the current  13 president of NISA and IMA, true?  14 A. Yes.  15 (Glenn Exhibit 7 marked for  16 identification.)  17 QUESTIONS BY MR. BOWDEN:  18 Q. Okay. I'm going to hand you  19 what I'm marking as Exhibit Number 7. This  20 is also going to be a web page from IMA-North  21 America entitled "Associate Members."  22 A. Yes.  23 Q. All right. So now, associate  24 members -- the producer members, those are  25 people that actually are producing minerals,</p>	<p style="text-align: right;">Page 65</p> <p>1 industrial sand section or the talc section,  2 they certainly can sit in on those meetings.  3 Q. Well, we're going to explore  4 some of that later on in your deposition.  5 A. All right. Okay.  6 MR. BOWDEN: So Mr. Smith, if  7 you'll go down about halfway down the  8 page, you'll see Crowell &amp; Moring,  9 LLP.  10 Will you please pull that out,  11 highlight the whole thing for us?  12 QUESTIONS BY MR. BOWDEN:  13 Q. You see as an associate member,  14 Crowell &amp; Moring, LLP, is listed, right?  15 A. Yes.  16 Q. And that's a law firm?  17 A. Yes, that's the firm I worked  18 for.  19 MR. DONATH: Note --  20 QUESTIONS BY MR. BOWDEN:  21 Q. That's a defense law firm,  22 right?  23 MR. DONATH: Note the same  24 objection. Beyond the scope. It's a  25 2018 document.</p>

17 (Pages 62 to 65)



Robert Glenn

Page 66	Page 68
<p>1 MR. DAVANT: Object to form. 2 THE WITNESS: Well, they're 3 principally a defense. They certainly 4 do pro bono work for individuals. 5 QUESTIONS BY MR. BOWDEN: 6 Q. Okay. 7 A. Plaintiffs. 8 Q. That's the firm that you ended 9 up working for after you left IMA-North 10 America? 11 A. I just mentioned that, yes. 12 Q. Okay. And then underneath 13 there it Glenn Consulting Group, two more 14 spaces down, right? 15 MR. DONATH: Same objection. 16 THE WITNESS: Yes, that's 17 correct. 18 QUESTIONS BY MR. BOWDEN: 19 Q. And of course, you wouldn't 20 have joined until Glenn Consulting existed in 21 2010, correct? 22 A. That's right. That was a 23 business decision on my part. I was getting 24 a three-quarter million dollars to do a 25 research study, and I thought the \$2500</p>	<p>1 members. So it usually came by the word of 2 mouth. 3 And I knew attorneys in 4 Crowell &amp; Moring while I was at IMA-NA, and 5 they may have been one of the founding 6 members, I'm not sure, founding associate 7 members. 8 Q. Which attorneys did you know at 9 Crowell &amp; Moring? 10 A. That were responsible for 11 working in this area, principally Edward 12 Green, Ed Green. 13 Q. What about Ridgway Hall? 14 A. I don't think -- he never 15 participated in any of the IMA-NA activities. 16 Q. Okay. 17 A. He was more of an environmental 18 lawyer. 19 Q. How did you meet Mr. Green? 20 A. I had been working in mining 21 for a long time, and I met him at MSHA 22 meetings. 23 Q. At what? 24 A. Mine Safety and Health 25 Administration meetings.</p>
Page 67	Page 69
<p>1 membership fee would be in my interest. 2 Q. Sure. 3 Crowell &amp; Moring, LLP, do you 4 recall when they first joined? 5 A. No. 6 There's a mining group -- a 7 small group in Crowell &amp; Moring that does 8 mining work, represents mining companies, 9 coal mining and other companies, and they 10 joined. I believe one of the counsel in that 11 litigation group was responsible for that. 12 Q. Okay. When you were the 13 president in 2002 through 2004, was Crowell &amp; 14 Moring a memory -- or excuse me. Strike 15 that. I misspoke. 16 When you were the president of 17 IMA-North America between 2002 and 2004, was 18 Crowell &amp; Moring a member, based on your 19 recollection? 20 A. I don't -- I don't recall if 21 they were or not. This -- the associate 22 member group was a kind of afterthought, if 23 you will. They were people we wanted to 24 join, but we didn't go out and try and 25 recruit them as the we we did the producer</p>	<p>1 Q. When is the earliest -- 2 A. Yeah, sorry. 3 Q. When was the earliest date that 4 you recall having a meetings with any lawyer 5 from Crowell &amp; Moring? 6 A. I probably -- well, I met 7 Mr. Green when I was in NIOSH. He was 8 general counsel at that time to the America 9 Mining Congress. And in my role as liaison 10 to industry, labor and government agencies, I 11 would meet with those groups, and I knew Ed 12 from that period. 13 Q. Did they represent Luzenac at 14 the time? 15 A. The American Mining Congress? 16 Q. No, no, what you just talked 17 about when you were at NIOSH. 18 You were the director head, 19 right? 20 A. Oh, yes. Yes. 21 Q. Crowell &amp; Moring, you were 22 speaking to some attorneys through your 23 position at NIOSH, right? 24 A. Right. 25 Q. As a liaison?</p>

18 (Pages 66 to 69)



Robert Glenn

Page 70	Page 72
<p>1 A. Yeah.</p> <p>2 Q. At that time when you're</p> <p>3 speaking to Crowell &amp; Moring attorneys, whose</p> <p>4 interests did they represent? Was it</p> <p>5 Luzenac?</p> <p>6 A. No.</p> <p>7 Q. It wasn't --</p> <p>8 A. Ed Green -- Ed Green was</p> <p>9 principally in coal mining -- worked in coal</p> <p>10 mining and represented coal companies. And</p> <p>11 again, going back -- this is going back to</p> <p>12 the -- to the 1980s.</p> <p>13 Q. Go ahead, sir.</p> <p>14 A. The American Mining Congress</p> <p>15 was one of the -- well, one of the largest,</p> <p>16 along with the national -- or the coal --</p> <p>17 coal mining had another association. Those</p> <p>18 two finally merged after Mr. Green left the</p> <p>19 firm.</p> <p>20 Q. Okay.</p> <p>21 A. Left the association and went</p> <p>22 to Crowell &amp; Moring.</p> <p>23 Q. Did you have interaction with</p> <p>24 Crowell &amp; Moring when you were the -- one of</p> <p>25 the officers of NISA?</p>	<p>1 MR. DAVANT: Object to form.</p> <p>2 THE WITNESS: -- discussion, I</p> <p>3 mean, they -- Crowell &amp; Moring, with</p> <p>4 Ed Green, would attend the meetings.</p> <p>5 He was aware we had talc companies,</p> <p>6 yes, as members.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. When was the first time that</p> <p>9 Crowell &amp; Moring spoke to you about coming to</p> <p>10 work for them?</p> <p>11 A. In 1988.</p> <p>12 Q. Did they want you to come</p> <p>13 in-house as a consulting scientist then?</p> <p>14 A. They wanted me to come in-house</p> <p>15 as vice president of industrial hygiene.</p> <p>16 Q. Okay. So did you maintain --</p> <p>17 from 1988 until 2004 when you ultimately went</p> <p>18 and joined their firm, did you maintain ties</p> <p>19 with them?</p> <p>20 A. We did for -- we had close ties</p> <p>21 for several years, and then it was just</p> <p>22 through running into maybe an attorney from</p> <p>23 Crowell &amp; Moring I knew at a meeting.</p> <p>24 Q. Okay. When was the first time</p> <p>25 you met Ridgway Hall?</p>
Page 71	Page 73
<p>1 A. Yes.</p> <p>2 Q. Okay. And did they represent</p> <p>3 the interests of some of the members in the</p> <p>4 NISA trade organization?</p> <p>5 A. I don't -- well, when you say</p> <p>6 "interests," it's broad. They represented</p> <p>7 NISA.</p> <p>8 Q. Oh, they represented NISA?</p> <p>9 A. Crowell &amp; Moring did.</p> <p>10 Q. I see.</p> <p>11 So when you were there at NISA,</p> <p>12 did you hire them?</p> <p>13 A. I hired them for one matter,</p> <p>14 yes.</p> <p>15 Q. What matter was that?</p> <p>16 A. That matter had to do with the</p> <p>17 litigation, silicosis litigation, in which</p> <p>18 the NISA was involved.</p> <p>19 Q. Okay. Did you have any</p> <p>20 discussion with Crowell &amp; Moring about talc</p> <p>21 while you were at NISA?</p> <p>22 A. No.</p> <p>23 Q. That discussion didn't come up</p> <p>24 until you were at IMA-North America, right?</p> <p>25 A. Well, when you say --</p>	<p>1 A. When I -- 2000 -- 2000 and --</p> <p>2 probably 2004, no doubt, when I went over to</p> <p>3 Crowell &amp; Moring.</p> <p>4 Q. Who extended to you the offer</p> <p>5 in 1988 to come and work for Crowell &amp;</p> <p>6 Moring, the defense law firm?</p> <p>7 MR. DAVANT: Object to form.</p> <p>8 THE WITNESS: David Siegel.</p> <p>9 QUESTIONS BY MR. BOWDEN:</p> <p>10 Q. Okay. Who contacted you about</p> <p>11 coming to work for them again in 2004? Was</p> <p>12 that Mr. Hall?</p> <p>13 A. No, that was David Siegel.</p> <p>14 Q. Again?</p> <p>15 A. I worked in the litigation</p> <p>16 group, and David was there. The mining group</p> <p>17 was separate.</p> <p>18 Q. I see.</p> <p>19 So when you left, went to</p> <p>20 NIOSH, the National -- NISA, you went to</p> <p>21 IMA-North America, and then when you went</p> <p>22 in-house with Crowell &amp; Moring --</p> <p>23 A. Right.</p> <p>24 Q. -- the defense attorneys --</p> <p>25 A. Yeah.</p>

19 (Pages 70 to 73)



Robert Glenn

<p style="text-align: right;">Page 74</p> <p>1 Q. -- you went into the litigation 2 department? 3 MR. DAVANT: Object to form. 4 THE WITNESS: Yes. 5 QUESTIONS BY MR. BOWDEN: 6 Q. You okay to keep going? 7 A. Sure. 8 Q. Okay. Great. 9 A. Sorry for getting -- losing my 10 voice. 11 Q. That's okay. 12 A. I'm on a medication, diuretic, 13 so I have to drink a lot of water. 14 Q. Now, I want to talk about 15 the -- after you left IMA-North America, did 16 you continue to interact with them, "them" 17 being IMA? 18 A. Yes. 19 Q. Okay. You never broke that 20 tie. You left from being president of 21 IMA-North America, you went into Crowell &amp; 22 Moring as a litigation department, and you 23 maintain that contact with IMA-North America, 24 right? 25 A. Yes.</p>	<p style="text-align: right;">Page 76</p> <p>1 them in the asbestos litigation department, 2 you then went and started interacting with 3 Imerys, correct? 4 MR. DONATH: Objection. Form. 5 MR. HEGARTY: Objection to 6 form. 7 THE WITNESS: Yeah, asbestos 8 litigation was not a department. It 9 was broadly litigation, product 10 liability, mass toxic tort. 11 But I worked with other groups 12 and provided them scientific support 13 as well outside of the litigation 14 support. 15 MR. BOWDEN: Okay. We're going 16 to switch gears. Now might be a good 17 time to take a break. 18 THE WITNESS: That's fine. 19 Yeah. 20 VIDEOGRAPHER: Okay. The time 21 is now 9:41. Going off the record. 22 (Off the record at 9:42 a.m.) 23 VIDEOGRAPHER: The time is now 24 9:55. Back on the record. 25</p>
<p style="text-align: right;">Page 75</p> <p>1 MR. DONATH: Objection to form. 2 QUESTIONS BY MR. BOWDEN: 3 Q. And when you went to work for 4 Crowell &amp; Moring law firm, was Luzenac 5 already a client? 6 A. No. Not to my knowledge, they 7 were not. 8 Q. Okay. What was the first 9 project you worked on when you went to 10 Crowell &amp; Moring? 11 A. It was -- 12 MR. DAVANT: Yeah, just caution 13 not to -- 14 THE WITNESS: Yeah. 15 MR. DAVANT: -- reveal any 16 client confidences. 17 THE WITNESS: Thank you. 18 It was asbestos litigation. 19 QUESTIONS BY MR. BOWDEN: 20 Q. Okay. Was that your sole 21 focus? 22 A. No. 23 Q. Was that your primary focus? 24 A. I'd say primary, yes. 25 Q. And then shortly after joining</p>	<p style="text-align: right;">Page 77</p> <p>1 QUESTIONS BY MR. BOWDEN: 2 Q. Just one more question on 3 that -- what we were just discussing. 4 Your involvement at IMA before 5 you left and went over to Crowell &amp; Moring, 6 at the time that you were at IMA-North 7 America, was anyone there dealing with the 8 issue of talc and ovarian cancer? 9 MR. DONATH: Objection to form. 10 THE WITNESS: Not that I 11 recall. The talc section -- I just 12 don't remember. It was just a short 13 two years. But, you know, now, given 14 the time you've mentioned, it's likely 15 they were discussing that during their 16 meetings. 17 QUESTIONS BY MR. BOWDEN: 18 Q. Is it fair to say that your 19 awareness or at least involvement with talc 20 and ovarian cancer did not start until you 21 went in-house at Crowell &amp; Moring? 22 A. That's when it -- 23 MR. HEGARTY: Objection. Form. 24 THE WITNESS: Yeah, when Imerys 25 came to us through Ridgway Hall,</p>

20 (Pages 74 to 77)



Robert Glenn

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<p>1 that's when I really started reading</p> <p>2 more about the ovarian cancer issue,</p> <p>3 as I recall.</p> <p>4 QUESTIONS BY MR. BOWDEN:</p> <p>5 Q. Okay. What month in 2004 did</p> <p>6 you start at Crowell &amp; Moring?</p> <p>7 A. It would have probably been</p> <p>8 June, possibly May, of 2004.</p> <p>9 Q. Okay.</p> <p>10 A. Around that time frame.</p> <p>11 Q. So -- all right. Now, I want</p> <p>12 to ask you: Prior to joining Crowell &amp;</p> <p>13 Moring in May of -- or excuse me, June</p> <p>14 of 2004 -- let me strike that.</p> <p>15 May, June 2004 --</p> <p>16 A. Yeah.</p> <p>17 Q. -- prior to joining Crowell &amp;</p> <p>18 Moring then, were you aware of Drs. Huncharek</p> <p>19 and Muscat?</p> <p>20 A. No, I didn't -- I wasn't aware</p> <p>21 of them until I got to Crowell &amp; Moring.</p> <p>22 Q. Prior to getting to Crowell &amp;</p> <p>23 Moring -- it's a poorly worded question. Let</p> <p>24 me strike it.</p> <p>25 Prior to joining Crowell &amp;</p>	<p>1 QUESTIONS BY MR. BOWDEN:</p> <p>2 Q. Sure.</p> <p>3 And they review a number of</p> <p>4 different things that they suspect might be</p> <p>5 carcinogens, right?</p> <p>6 MR. HEGARTY: Objection. Form.</p> <p>7 THE WITNESS: Yeah, they come</p> <p>8 under -- their role comes under an act</p> <p>9 that was passed by Congress to put out</p> <p>10 what used to be called an annual</p> <p>11 report on carcinogens.</p> <p>12 QUESTIONS BY MR. BOWDEN:</p> <p>13 Q. Right.</p> <p>14 A. They weren't meeting the</p> <p>15 annual, but they still are doing that --</p> <p>16 Q. Well, and you --</p> <p>17 A. -- to my knowledge.</p> <p>18 Q. I'm sorry.</p> <p>19 A. Yeah.</p> <p>20 Q. And you know that in 2000, talc</p> <p>21 was nominated for review, right?</p> <p>22 A. I -- I know -- yes, now.</p> <p>23 When I was reviewing some of</p> <p>24 these documents, I did not recall that they</p> <p>25 had had an original review of talc.</p>
Page 79	Page 81
<p>1 Moring, had you ever contacted the</p> <p>2 Meta-Analysis Research Group?</p> <p>3 A. No.</p> <p>4 Q. Did you even know what the</p> <p>5 Meta-Analysis Research Group was prior to</p> <p>6 joining Crowell &amp; Moring?</p> <p>7 A. No.</p> <p>8 Q. Now, I want to take you just a</p> <p>9 step back and just talk generally about the</p> <p>10 NTP report on carcinogens process.</p> <p>11 Are you familiar with that</p> <p>12 process?</p> <p>13 A. I'm -- yes, I'm familiar with</p> <p>14 it.</p> <p>15 Q. Okay. Was that something that</p> <p>16 you closely followed while you were at</p> <p>17 IMA-North America?</p> <p>18 MR. DONATH: Objection. Form.</p> <p>19 THE WITNESS: I think at that</p> <p>20 time they were -- they did have a</p> <p>21 silica -- possibly were looking at</p> <p>22 silica through -- to put it through</p> <p>23 the NTP review process, so I may</p> <p>24 have -- I may have been.</p> <p>25</p>	<p>1 Q. And I think that's fair. And I</p> <p>2 want to make very clear for the record and</p> <p>3 whoever else might be watching this, you</p> <p>4 didn't have a recollection prior to reading</p> <p>5 the documents in preparation for this</p> <p>6 deposition as to that first NTP process,</p> <p>7 correct?</p> <p>8 A. Yeah, I wasn't really involved</p> <p>9 in -- or to my recall, I don't remember being</p> <p>10 tuned in to that first review.</p> <p>11 Q. Right.</p> <p>12 And the NTP process that I'm</p> <p>13 speaking of is specifically dealing with the</p> <p>14 nomination of talc.</p> <p>15 A. That's correct, yeah.</p> <p>16 Q. That didn't -- wasn't something</p> <p>17 you were focused on, wasn't something that</p> <p>18 you were devoting your time or services to</p> <p>19 prior to joining Crowell &amp; Moring in May,</p> <p>20 June 2004, right?</p> <p>21 A. Yeah, that's right. And it</p> <p>22 wasn't immediately May, June, when I got</p> <p>23 focused on it at Crowell &amp; Moring. It was</p> <p>24 sometime later --</p> <p>25 Q. Okay.</p>

21 (Pages 78 to 81)



Robert Glenn

<p style="text-align: right;">Page 82</p> <p>1 A. -- that Imerys came to our 2 firm. 3 Q. And we're going to explore that 4 in a minute, but I'm just trying to flesh out 5 your knowledge and understanding of the NTP 6 process. 7 A. Yeah. 8 Q. And we're going to build from 9 there, all right? 10 A. Yeah. 11 Q. So let me ask you the next 12 question. Okay? 13 So that 2000 NTP process, that 14 was known as the tenth report on carcinogens, 15 right? 16 A. If you say so, yes, I'll accept 17 that. 18 Q. Okay. And did you know -- or 19 do you know that the NTP ultimately deferred 20 the issue of whether talc is a carcinogen 21 during the 10 ROC process? 22 MR. DONATH: Objection. Form. 23 MR. HEGARTY: Objection. Form. 24 THE WITNESS: I learned that 25 when I was reviewing some of the</p>	<p style="text-align: right;">Page 84</p> <p>1 MR. DONATH: Objection to form. 2 MR. HEGARTY: Objection to 3 form. 4 THE WITNESS: I have not read 5 that review. I'm accepting what 6 you're saying, but I haven't read the 7 action they took at the tenth 8 report -- 9 QUESTIONS BY MR. BOWDEN: 10 Q. Sure. 11 A. -- for talc. 12 Q. When you started at Crowell &amp; 13 Moring, you did not believe at that time that 14 the NTP had ruled that talc was not a 15 carcinogen, correct? 16 MR. DAVANT: Objection. Form. 17 THE WITNESS: I was not aware 18 of that at all. 19 MR. DONATH: Join. 20 QUESTIONS BY MR. BOWDEN: 21 Q. Okay. And in fact what 22 happened was, the 10th Report on Carcinogens 23 deferred the issue for a later date, right? 24 MR. HEGARTY: Objection to 25 form.</p>
<p style="text-align: right;">Page 83</p> <p>1 materials through this deposition. 2 QUESTIONS BY MR. BOWDEN: 3 Q. So that wasn't a fact that you 4 already knew when you joined Crowell &amp; 5 Moring? 6 A. No. 7 One thing on the talc -- 8 Q. I'm sorry, sir, I'm going to 9 continue with my questions, and your counsel 10 will have an opportunity to ask questions as 11 well. 12 A. Okay. All right. Fine. 13 Q. So they deferred the issue. 14 They didn't vote that it was not a carcinogen 15 during the 10th Report on Carcinogens, 16 correct? 17 MR. HEGARTY: Objection. Form. 18 THE WITNESS: That's my 19 understanding, yes, sir. 20 QUESTIONS BY MR. BOWDEN: 21 Q. So it would be -- if someone 22 were to walk into court in this proceeding 23 and say that in 2000, the NTP found that talc 24 was not a carcinogen, that would not be 25 accurate, correct?</p>	<p style="text-align: right;">Page 85</p> <p>1 THE WITNESS: That's what I -- 2 I saw some documents related to that, 3 but it did not include the tenth 4 report. 5 QUESTIONS BY MR. BOWDEN: 6 Q. Okay. And when you're saying 7 "some documents," you're talking about in 8 preparation for today? 9 A. Yes. 10 Q. Okay. That wasn't vital 11 information for you to understand during your 12 employment at Crowell &amp; Moring, right? 13 MR. DONATH: Objection to form. 14 MR. DAVANT: Objection to form. 15 THE WITNESS: The tenth report? 16 QUESTIONS BY MR. BOWDEN: 17 Q. Yeah. 18 A. No. 19 Q. No one printed it out for you 20 and put it on your desk to make you familiar 21 with it, right? 22 MR. DONATH: Objection to form. 23 THE WITNESS: The tenth report? 24 QUESTIONS BY MR. BOWDEN: 25 Q. Yes, sir.</p>

22 (Pages 82 to 85)



Robert Glenn

Page 86	Page 88
<p>1 A. No, I --</p> <p>2 Q. Okay. Now, when -- at some</p> <p>3 point talc was renominated for inclusion on</p> <p>4 the report of carcinogens, right?</p> <p>5 A. Yes.</p> <p>6 Q. That was for the 12th report,</p> <p>7 correct?</p> <p>8 A. I'm not sure what the date of</p> <p>9 that was. I'll accept that it was the 12th.</p> <p>10 Q. Well, I'll represent to you</p> <p>11 that it was renominated in May of 2004.</p> <p>12 Does that sound correct to you?</p> <p>13 A. I don't know of that date. If</p> <p>14 you -- if you are representing that, I will</p> <p>15 accept that.</p> <p>16 Q. Okay. And when you started at</p> <p>17 Crowell &amp; Moring and you were put on the</p> <p>18 issue of talc and ovarian cancer in the</p> <p>19 litigation department, did you go back and</p> <p>20 look at what had been published since the</p> <p>21 10th ROC and the 12th ROC nomination?</p> <p>22 MR. HEGARTY: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: I started</p> <p>25 reviewing the medical literature</p>	<p>1 then even afterwards as Glenn Consulting,</p> <p>2 right?</p> <p>3 MR. HEGARTY: Objection. Form.</p> <p>4 THE WITNESS: I don't think</p> <p>5 I've ever had any contact with him</p> <p>6 after leaving Crowell &amp; Moring.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. Okay. So only while you were</p> <p>9 at Crowell &amp; Moring did you have contact</p> <p>10 directly with Steven Mann?</p> <p>11 MR. HEGARTY: Objection. Form.</p> <p>12 THE WITNESS: That's my recall,</p> <p>13 yes.</p> <p>14 QUESTIONS BY MR. BOWDEN:</p> <p>15 Q. And you can see that he's the</p> <p>16 director of toxicology at Johnson &amp; Johnson</p> <p>17 Consumer Personal Care Products Worldwide.</p> <p>18 Do you see that there?</p> <p>19 A. Yeah, correct.</p> <p>20 Q. Okay. And this is a June 4,</p> <p>21 2004 e-mail.</p> <p>22 Do you see where I'm reading</p> <p>23 from?</p> <p>24 A. Date, date, date...</p> <p>25 Q. It's at the very top, sir.</p>
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<p>1 related to talc, but I don't think</p> <p>2 that I ever went back and reviewed the</p> <p>3 transactions from the tenth report.</p> <p>4 QUESTIONS BY MR. BOWDEN:</p> <p>5 Q. Okay.</p> <p>6 A. But that's when I started to</p> <p>7 hone in on talc and ovarian cancer, to my</p> <p>8 knowledge.</p> <p>9 (Glenn Exhibit 8 marked for</p> <p>10 identification.)</p> <p>11 QUESTIONS BY MR. BOWDEN:</p> <p>12 Q. Okay. I'm going to mark for</p> <p>13 you what's going to be Exhibit Number 8.</p> <p>14 MR. BOWDEN: Corey, if you</p> <p>15 would, highlight the date at the top</p> <p>16 for us along with who the sender is.</p> <p>17 QUESTIONS BY MR. BOWDEN:</p> <p>18 Q. Now, Mr. Glenn, you know who</p> <p>19 Steven Mann is, don't you?</p> <p>20 A. I know of Steven Mann. I have</p> <p>21 been on telephone conversations with him. I</p> <p>22 don't know if I ever met Steven Mann.</p> <p>23 Q. Okay. But you've had a number</p> <p>24 of conversations with him over your course of</p> <p>25 your employment with Crowell &amp; Moring and</p>	<p>1 I've got it highlighted for you on the</p> <p>2 screen.</p> <p>3 A. Yeah, that's --</p> <p>4 Q. Do you see that?</p> <p>5 A. Yes.</p> <p>6 Q. So this would have been, to</p> <p>7 your knowledge, about the time that you were</p> <p>8 joining the Crowell &amp; Moring law firm, right?</p> <p>9 A. Yes.</p> <p>10 MR. BOWDEN: And, Corey, if we</p> <p>11 can go down to the body of the e-mail</p> <p>12 where it says "the Talc Task Force</p> <p>13 conference call" in the middle.</p> <p>14 Okay. And we'll expand that</p> <p>15 down to show who the participants</p> <p>16 were.</p> <p>17 QUESTIONS BY MR. BOWDEN:</p> <p>18 Q. And I should point out, too,</p> <p>19 the subject of this e-mail was the CTFA talc</p> <p>20 conference call minutes.</p> <p>21 You know what the CTFA is?</p> <p>22 A. Yes, it was the cosmetic</p> <p>23 toiletries fragrance association.</p> <p>24 Q. Right. And that's another</p> <p>25 trade organization, right?</p>

23 (Pages 86 to 89)



Robert Glenn

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<p>1 A. That's correct.</p> <p>2 Q. And it represents the interests</p> <p>3 or has members that include talc</p> <p>4 manufacturers and producers of consumer</p> <p>5 products such as Johnson &amp; Johnson, right?</p> <p>6 MR. BILLINGS-KANG: Object to</p> <p>7 form.</p> <p>8 A. Yes, it does.</p> <p>9 QUESTIONS BY MR. BOWDEN:</p> <p>10 Q. Okay. And this talc force, you</p> <p>11 can see that Steven Mann was on the call for</p> <p>12 Johnson &amp; Johnson.</p> <p>13 You see that?</p> <p>14 A. Yes.</p> <p>15 Q. And you also see that Rich</p> <p>16 Zazenski with Luzenac was on that call as</p> <p>17 well, right?</p> <p>18 A. Yes.</p> <p>19 MR. DONATH: Going to assert an</p> <p>20 objection to the line of questioning</p> <p>21 just insofar as Mr. Glenn isn't a</p> <p>22 recipient or a sender on this e-mail.</p> <p>23 QUESTIONS BY MR. BOWDEN:</p> <p>24 Q. And then if you go down to the</p> <p>25 bottom, it says, "since the first review was</p>	<p>1 Q. And do you understand that in</p> <p>2 the context of our timeline here, talc has</p> <p>3 now been renominated for the NTP process?</p> <p>4 You understand that, right?</p> <p>5 A. Yes.</p> <p>6 Q. And that's consistent with your</p> <p>7 understanding of some of the things you were</p> <p>8 going to be working on very shortly at</p> <p>9 Crowell &amp; Moring law firm, right?</p> <p>10 A. I'm sorry, would you repeat</p> <p>11 that?</p> <p>12 Q. It was a little bit of a long</p> <p>13 question.</p> <p>14 A. Well, I was trying to read the</p> <p>15 paragraph.</p> <p>16 Q. Okay. So you understand that</p> <p>17 at this time, in June of 2004 --</p> <p>18 A. Yeah.</p> <p>19 Q. -- as you're beginning your</p> <p>20 employment at Crowell &amp; Moring, talc has been</p> <p>21 renominated for the 12th Report on</p> <p>22 Carcinogens, right?</p> <p>23 MR. HEGARTY: Objection. Form.</p> <p>24 THE WITNESS: I don't know if I</p> <p>25 knew it at this time or not.</p>
Page 91	Page 93
<p>1 complete."</p> <p>2 Do you see that there?</p> <p>3 A. Yes.</p> <p>4 Q. It says, "Since the first</p> <p>5 review was completed, a meta-analysis has</p> <p>6 been published, Huncharek, et al. The</p> <p>7 authors found a weak association,</p> <p>8 statistically significant, between talc and</p> <p>9 ovarian cancer but did not conclude there was</p> <p>10 a causal association."</p> <p>11 Do you see that there?</p> <p>12 A. Yes.</p> <p>13 Q. "CTFA will contact the authors</p> <p>14 to get more insight into their position and</p> <p>15 the study."</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Now, prior to this date, to the</p> <p>19 best of your knowledge, you had not had any</p> <p>20 direct correspondence with Dr. Huncharek,</p> <p>21 Dr. Muscat or the MRG Group, right?</p> <p>22 A. No, I had not.</p> <p>23 Q. Okay. Turn to the second page,</p> <p>24 please. It's the middle paragraph there.</p> <p>25 A. Okay.</p>	<p>1 QUESTIONS BY MR. BOWDEN:</p> <p>2 Q. Okay.</p> <p>3 A. It's likely I did not -- I</p> <p>4 didn't know it until Luzenac came to us.</p> <p>5 Q. Okay. And we can see on this</p> <p>6 e-mail that Johnson &amp; Johnson, Luzenac and</p> <p>7 others are participating in a CTFA conference</p> <p>8 call, right?</p> <p>9 A. Correct.</p> <p>10 MR. DONATH: Same objection.</p> <p>11 MR. BILLINGS-KANG: Objection.</p> <p>12 He doesn't have any personal knowledge</p> <p>13 as to the e-mail.</p> <p>14 QUESTIONS BY MR. BOWDEN:</p> <p>15 Q. And then we go to the second</p> <p>16 page. It says, "For the first comment</p> <p>17 period, it was suggested that the previous</p> <p>18 submissions related to ovarian cancer be</p> <p>19 resubmitted."</p> <p>20 You weren't involved in any way</p> <p>21 with the first submissions, right, for the 10</p> <p>22 ROC?</p> <p>23 A. No. To my knowledge, I didn't</p> <p>24 have anything to do with that.</p> <p>25 Q. "And updated with the addition</p>

24 (Pages 90 to 93)



Robert Glenn

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<p>1 of the limited new information, i.e., the 2 Huncharek paper." 3 Do you see that there? 4 A. Yes. 5 MR. DONATH: Same objection. 6 The witness did not send or receive 7 this e-mail, hasn't said he has 8 personal knowledge of it. 9 QUESTIONS BY MR. BOWDEN: 10 Q. "It was suggested that the CTFA 11 express surprise over the renomination of 12 talc." 13 Do you see where that's 14 written? 15 A. Yes. 16 Q. "Given the outcome of the board 17 meeting in 2000 and the fact there is no new 18 cause for concern." 19 Do you see that? 20 A. I see that. 21 Q. And your client, Luzenac, was a 22 member -- or a participant of this 23 conference, right? 24 MR. DONATH: Objection to form. 25 THE WITNESS: Yes, there was a</p>	<p>1 Q. And it can also have -- if talc 2 were to be considered a carcinogen, that 3 would have important business ramifications 4 too, right? 5 MR. DONATH: Objection to form. 6 MR. HEGARTY: Objection to 7 form. 8 THE WITNESS: I would think it 9 would. 10 QUESTIONS BY MR. BOWDEN: 11 Q. Okay. In what way would it 12 have business ramifications? 13 MR. DONATH: Objection to form. 14 MR. BILLINGS-KANG: Objection 15 to form. 16 THE WITNESS: Possibly the 17 reason we're here today: litigation. 18 QUESTIONS BY MR. BOWDEN: 19 Q. Was that a consideration back 20 in 2004? 21 MR. DONATH: Same objection. 22 THE WITNESS: I don't know. I 23 wasn't involved in this. 24 QUESTIONS BY MR. BOWDEN: 25 Q. Okay. We're --</p>
Page 95	Page 97
<p>1 Luzenac employee at the meeting -- at 2 the conference call. 3 QUESTIONS BY MR. BOWDEN: 4 Q. And it's fair to say that this 5 was an important issue, talc and ovarian 6 cancer, right? 7 MR. HEGARTY: Objection. 8 MR. DONATH: Objection to form. 9 MR. BILLINGS-KANG: Objection 10 to form. 11 THE WITNESS: I don't know. At 12 this time I don't know what CTFA 13 considered it. 14 QUESTIONS BY MR. BOWDEN: 15 Q. Well, I'm not asking you what 16 they considered it. I'm asking whether 17 ovarian cancer, is that a serious condition? 18 A. It's a very serious condition. 19 Q. It causes death, right? 20 A. It does have a high mortality 21 rate because of lateness of diagnosis. 22 Q. It's an exceptionally high 23 mortality rate in terms of gynecological 24 cancers, right? 25 A. Yes, it is.</p>	<p>1 A. I don't know -- 2 Q. -- going to see about that. 3 A. -- what these people were 4 talking about, what they were discussing. 5 All I have are these minutes you've given me. 6 Q. Sure. 7 If talc were to be considered a 8 carcinogen, that might require labeling to be 9 added to talcum products, right? 10 MR. HEGARTY: Objection. 11 MR. BILLINGS-KANG: Objection. 12 Form. 13 THE WITNESS: Yes. I'm sorry, 14 I don't know what the FDA regulations 15 are for labeling. 16 At the time I made my first 17 answer, I was thinking of OSHA 18 regulations. And if it's going into 19 the industry, it would have to be 20 labeled. 21 QUESTIONS BY MR. BOWDEN: 22 Q. Yeah. Things like MSDSs would 23 need to be updated? 24 MR. HEGARTY: Objection. Form. 25 MR. BILLINGS-KANG: Objection.</p>

25 (Pages 94 to 97)



Robert Glenn

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<p>1 Form.</p> <p>2 THE WITNESS: I'm not sure.</p> <p>3 MSDSs are for workers in industry.</p> <p>4 QUESTIONS BY MR. BOWDEN:</p> <p>5 Q. Uh-huh.</p> <p>6 A. They're not for the general</p> <p>7 public.</p> <p>8 Q. Right.</p> <p>9 A. Again, I'm not an FDA</p> <p>10 specialist at all, so I don't know what their</p> <p>11 regulations would require concerning any type</p> <p>12 of a decision by the NTP.</p> <p>13 Q. Haven't you issued expert</p> <p>14 reports in the past regarding MSDSs and</p> <p>15 whether they need to be updated for</p> <p>16 carcinogen warnings?</p> <p>17 A. I have related to OSHA in</p> <p>18 industry, general industry, maritime,</p> <p>19 agriculture.</p> <p>20 Q. Right.</p> <p>21 A. Not for the consumers.</p> <p>22 Q. Right.</p> <p>23 Well, consumers aren't given</p> <p>24 MSDSs, right?</p> <p>25 A. I'm sorry, I didn't finish.</p>	<p>1 Q. Okay. And it's important those</p> <p>2 be accurate?</p> <p>3 A. Oh, yes.</p> <p>4 Q. And it's important they be</p> <p>5 updated?</p> <p>6 A. Yes.</p> <p>7 Q. And it's important that the</p> <p>8 information that's contained in there gets to</p> <p>9 the end user, right?</p> <p>10 MR. DAVANT: Objection. Form.</p> <p>11 QUESTIONS BY MR. BOWDEN:</p> <p>12 Q. When I say "end user," I mean</p> <p>13 the person who's going to be reprocessing</p> <p>14 this into something else.</p> <p>15 MR. HEGARTY: Objection. Form.</p> <p>16 THE WITNESS: When you say "end</p> <p>17 user," I'm thinking about the person</p> <p>18 on the factory floor.</p> <p>19 QUESTIONS BY MR. BOWDEN:</p> <p>20 Q. Right. That's what I'm asking</p> <p>21 you.</p> <p>22 A. Not the consumer, not someone</p> <p>23 in their home --</p> <p>24 Q. Right.</p> <p>25 A. -- but on the factory floor.</p>
Page 99	Page 101
<p>1 MSDSs are not intended for</p> <p>2 consumers or for the public.</p> <p>3 Q. Right.</p> <p>4 A. Right.</p> <p>5 Q. Those are considered to be</p> <p>6 industry internal to the -- to -- say a</p> <p>7 manufacturer produces a mineral, and that</p> <p>8 mineral has an MSDS that goes to the end</p> <p>9 user, which might be a company that</p> <p>10 reprocesses it for the general public, right?</p> <p>11 MR. DONATH: Objection to form.</p> <p>12 THE WITNESS: Well, it goes to</p> <p>13 a company, and then from there it</p> <p>14 goes -- is to go downstream to the</p> <p>15 individual workers --</p> <p>16 QUESTIONS BY MR. BOWDEN:</p> <p>17 Q. Right.</p> <p>18 A. -- so they're informed of the</p> <p>19 hazards of the products they're working with.</p> <p>20 Q. Right.</p> <p>21 And it's the company that</p> <p>22 creates the MSDS, right?</p> <p>23 A. Yes.</p> <p>24 Q. The manufacturer?</p> <p>25 A. Yes.</p>	<p>1 It's very important it get there because --</p> <p>2 in my opinion, MSDSs don't quite get done</p> <p>3 what needs to be done. But they're to inform</p> <p>4 the employee of the hazards so they can</p> <p>5 modify their behavior and reduce their risk.</p> <p>6 Q. I think that's a very succinct</p> <p>7 way of saying it.</p> <p>8 A. Yeah.</p> <p>9 Q. And that information is given</p> <p>10 to employees on the factory floor, in your</p> <p>11 example --</p> <p>12 A. Yes.</p> <p>13 Q. -- so that they can modify</p> <p>14 their behavior and reduce their risk --</p> <p>15 A. Yes.</p> <p>16 Q. -- correct?</p> <p>17 And that's --</p> <p>18 A. First of all, the industry has</p> <p>19 obligation to reduce that risk through</p> <p>20 engineering controls and such.</p> <p>21 Q. No question. No question.</p> <p>22 But the MSDSs aren't given to</p> <p>23 consumers, to people like young women who are</p> <p>24 going and buying talcum products off the</p> <p>25 shelf, right?</p>

26 (Pages 98 to 101)



Robert Glenn

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<p>1 A. No, they're not.</p> <p>2 Q. The designation of talc as a</p> <p>3 carcinogen might also cause increased</p> <p>4 regulations to be imposed, correct?</p> <p>5 MR. DONATH: Objection. Form.</p> <p>6 MR. HEGARTY: Objection. Form.</p> <p>7 THE WITNESS: It could, yes.</p> <p>8 QUESTIONS BY MR. BOWDEN:</p> <p>9 Q. And you already mentioned that</p> <p>10 it might open up manufacturers and producers</p> <p>11 like Imerys and J&amp;J up to lawsuits, correct?</p> <p>12 MR. DONATH: Objection. Form.</p> <p>13 MR. HEGARTY: Objection. Form.</p> <p>14 THE WITNESS: Yes, that would</p> <p>15 be a possible outcome.</p> <p>16 (Glenn Exhibit 9 marked for</p> <p>17 identification.)</p> <p>18 QUESTIONS BY MR. BOWDEN:</p> <p>19 Q. I'm going to hand you what I'm</p> <p>20 going to mark as Exhibit Number 9. Bear with</p> <p>21 me a second. I think we're going to cut</p> <p>22 through some of this.</p> <p>23 And those factors that we've</p> <p>24 just gone over, those are factors that you</p> <p>25 understood the whole time you were working at</p>	<p>1 A. Yes.</p> <p>2 Q. And this is dated August 18,</p> <p>3 2004. It's to Ridgway Hall.</p> <p>4 Was he the partner you were</p> <p>5 working with most closely at that point?</p> <p>6 A. He was. He was responsible for</p> <p>7 this matter, the attorney responsible for</p> <p>8 this matter.</p> <p>9 Q. All right. Now, I want to turn</p> <p>10 to the second page here.</p> <p>11 A. Okay.</p> <p>12 Q. And you can see that he's</p> <p>13 attaching a study.</p> <p>14 Have you seen the study before?</p> <p>15 A. Some time ago I did read this</p> <p>16 study, yes.</p> <p>17 Q. And this is the Mills study,</p> <p>18 right?</p> <p>19 A. Yes.</p> <p>20 Q. The author is Mills?</p> <p>21 A. The major -- the principal</p> <p>22 author, yes.</p> <p>23 Q. And the title of the article</p> <p>24 here -- and this is a peer-reviewed article,</p> <p>25 right?</p>
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<p>1 Crowell &amp; Moring, right?</p> <p>2 MR. DAVANT: Object to form.</p> <p>3 MR. DONATH: Form.</p> <p>4 THE WITNESS: The factors</p> <p>5 related to MSDS sheets?</p> <p>6 QUESTIONS BY MR. BOWDEN:</p> <p>7 Q. All the factors we just talked</p> <p>8 about. If ovarian cancer -- if talc was</p> <p>9 related to ovarian cancer, that would cause</p> <p>10 this cascade of factors --</p> <p>11 MR. DONATH: Objection. Form.</p> <p>12 MR. BILLINGS-KANG: Objection.</p> <p>13 Form.</p> <p>14 QUESTIONS BY MR. BOWDEN:</p> <p>15 Q. -- to taken into consideration?</p> <p>16 MR. BILLINGS-KANG: Objection.</p> <p>17 Form.</p> <p>18 THE WITNESS: Yes.</p> <p>19 QUESTIONS BY MR. BOWDEN:</p> <p>20 Q. So now I'm going to hand you</p> <p>21 Exhibit 9.</p> <p>22 All right. I want to turn to</p> <p>23 the cover page of this. This is actually a</p> <p>24 fax from Luzenac to Crowell &amp; Moring.</p> <p>25 Do you see that there?</p>	<p>1 A. It is.</p> <p>2 Q. And you're familiar with the</p> <p>3 peer-review process. You've actually gone</p> <p>4 through it yourself, right?</p> <p>5 A. Yes.</p> <p>6 Q. And let me just ask you some</p> <p>7 general questions about peer review</p> <p>8 generally.</p> <p>9 The byline, who goes on a</p> <p>10 byline?</p> <p>11 A. A byline. You mean --</p> <p>12 Q. Who gets credited with</p> <p>13 authorship?</p> <p>14 A. The author?</p> <p>15 Q. Yes, sir.</p> <p>16 A. You have to have contributed a</p> <p>17 major part to the study.</p> <p>18 Q. And you can contribute in a</p> <p>19 number of different ways. It doesn't</p> <p>20 necessarily mean actually typing out the</p> <p>21 words, right?</p> <p>22 MR. HEGARTY: Objection.</p> <p>23 THE WITNESS: It means you have</p> <p>24 to have a significant input to the</p> <p>25 study.</p>

27 (Pages 102 to 105)



Robert Glenn

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<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. Uh-huh. 3 A. Merely reviewing the study and 4 the edit and commenting is not sufficient. 5 Q. Okay. 6 A. It may have been done in the 7 past; it's not done today. 8 Q. It's considered inappropriate 9 today? 10 A. Yes. 11 Q. Okay. And when did that 12 transition occur? 13 A. I think it's taken place since 14 maybe starting with 2000. It depends on the 15 journal. 16 Q. Okay. 17 A. But it used to be that, you 18 know, a research group would list a whole 19 number of coauthors who maybe were in the 20 team and maybe reviewed it, maybe offered 21 comments, maybe went through a discussion, 22 but they did not contribute to the research 23 and the writing of the manuscript. 24 Q. And, sir, I apologize, I 25 coughed right in the middle of your answer.</p>	<p>1 A. Yes, that's what it says. 2 Q. And just underneath that it 3 says, "Received January 14th; accepted May 3, 4 2004." 5 Do you see where that's 6 written? 7 A. Yes. 8 Q. And so this was one of the 9 papers that had come out, too, since the 10th 10 Report on Carcinogen, right? 11 A. Yes. 12 Q. And this actually came out and 13 was published in May of 2004, correct? 14 A. Yes. 15 Q. The same month that Crowell &amp; 16 Moring asked you to come over to work for 17 them at their law firm, right? 18 A. Same month I -- I recall 19 joining Crowell &amp; Moring, yes. 20 Q. And the takeaway from this 21 paper -- I'm not asking you whether you agree 22 with it or not. But takeaway the authors 23 say, they suggest that there is an increased 24 risk between perineal talc use and ovarian 25 cancer, correct?</p>
Page 107	Page 109
<p>1 A. That's all right. 2 Q. Did I hear you correctly that 3 they wouldn't be considered authors because 4 they did not contribute to the research or 5 the writing of the paper? Correct? 6 A. Yes. 7 Q. All right. So let's look here 8 under the abstract. It says, "Perineal talc 9 use has been suggested as a possible risk 10 factor for ovarian cancer based on the 11 structural similarity to asbestos, a known 12 human carcinogen." 13 Do you see where that's 14 written? 15 A. Yes, and that's a poor 16 sentence. 17 Q. I'm just asking, do you see 18 where it's written, sir? 19 A. I see where it's written. 20 Q. At the bottom of the abstract 21 it says, "This study provides some support 22 for the hypothesis that perineal talc use is 23 associated with an increased risk of EOC." 24 And you understand that to mean 25 epithelial ovarian cancer, right?</p>	<p>1 MR. DONATH: Objection. Form. 2 MR. BILLINGS-KANG: Objection 3 to form. 4 THE WITNESS: I haven't read 5 this document in a long time, 6 carefully, but I remember being 7 critical of this document. That's 8 what they say. 9 QUESTIONS BY MR. BOWDEN: 10 Q. Sure. 11 And I understand you've been 12 critical all along of the concept of talc and 13 its ability to cause ovarian cancer, correct? 14 MR. DONATH: Objection to form. 15 THE WITNESS: I haven't been 16 critical all along. I've read the 17 literature and formed my scientific 18 opinion after carefully considering 19 the literature. 20 QUESTIONS BY MR. BOWDEN: 21 Q. Once you started at Crowell &amp; 22 Moring? 23 A. Once I started at Crowell &amp; 24 Moring is my recollection of when I got 25 involved in talc and ovarian cancer.</p>

28 (Pages 106 to 109)



Robert Glenn

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<p>1 Q. And you're aware that other 2 people have looked at the same studies and 3 information and disagree with you on that 4 topic? 5 MR. HEGARTY: Objection to 6 form. 7 MR. DONATH: Objection to form. 8 THE WITNESS: Well, let's look 9 at IARC. 10 QUESTIONS BY MR. BOWDEN: 11 Q. I'm just asking you -- 12 A. Yeah. 13 Q. -- are you aware that other 14 people looking at the same data disagree with 15 you? 16 A. And there are a number that 17 agree, but, yes. 18 Q. So this gets issued in May 19 of 2004, right? 20 A. Yes. 21 Q. And in May of 2004, talc is 22 renominated for consideration on the Report 23 on Carcinogens, right? 24 A. I believe so, yes. 25 Q. And at that same time, you are</p>	<p>1 okay? So I want you to go ahead and turn to 2 the last page here. 3 A. Let me just thumb through it so 4 I get a -- somewhat of a context. Okay. 5 Q. Now, let me ask you -- 6 A. When you say "the back," do you 7 mean the e-mail? 8 Q. Yes, sir, the very last page of 9 the exhibit. 10 A. Right. 11 Q. And so I use a coding system at 12 the bottom. You see where it says P1-0187.5? 13 A. I do. 14 Q. Now you're on .5? 15 A. Yes. 16 Q. Great. 17 So let me just ask you a couple 18 of just general questions before we get into 19 this document here. 20 Who was it that first put you 21 in contact with Meta-Analysis Research Group? 22 MR. DONATH: I want to give a 23 direction to the witness as well that 24 we're probably going to be wading into 25 some areas here, and I'm going to</p>
Page 111	Page 113
<p>1 now being pulled away from the industry trade 2 organization and going to work for a law firm 3 that ends up defending and advancing the 4 interests of one of the talc manufacturers, 5 correct? 6 MR. DONATH: Objection to form. 7 THE WITNESS: I wasn't pulled 8 away. 9 QUESTIONS BY MR. BOWDEN: 10 Q. That's right, you weren't -- it 11 was a voluntary decision, right? 12 A. Yes, it was a voluntary 13 decision to accept employment. And I wasn't 14 pulled away because of talc. As I said 15 earlier, I was mainly involved in asbestos 16 litigation. 17 (Glenn Exhibit 10 marked for 18 identification.) 19 QUESTIONS BY MR. BOWDEN: 20 Q. Okay. We're going to get to 21 that in a minute. 22 All right. I'm going to hand 23 you what I'm marking as Exhibit Number 10. 24 And because of the way this document's 25 written, we're going to start from the back,</p>	<p>1 remind you and ask you not to divulge 2 any discussions or information that 3 might have been within the purview of 4 the privilege of Imerys while you were 5 at Crowell &amp; Moring. 6 QUESTIONS BY MR. BOWDEN: 7 Q. You understood my question. My 8 question was, who first introduced you to 9 Meta-Analysis Research Group? 10 You can answer that question. 11 Go ahead. 12 A. I found -- well, I found 13 Dr. Huncharek when I was looking for an 14 asbestos researcher for asbestos litigation. 15 Q. When was that? 16 A. That was in -- earlier in this 17 year. 18 Q. Earlier in 2004 -- 19 A. As I recall. 20 Q. -- right? 21 A. Yeah. 22 Q. You say "this year." I want to 23 make clear for the record that's 2004. 24 A. Yeah. 25 Q. Okay.</p>

29 (Pages 110 to 113)



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<p>1 A. As I recall, he was a 2 pathologist -- he is a pathologist, and I was 3 looking for a pathologist on asbestos. He 4 had published on that subject, and his name 5 is the one that I pulled up in searching for 6 pathologists to work on asbestos. We did not 7 use him for that. 8 Q. Why not? 9 A. We found others that we thought 10 more acceptable pathologists. 11 Q. When you say "more acceptable," 12 you mean more qualified? 13 MR. HEGARTY: Objection. Form. 14 THE WITNESS: No, I mean they 15 had somewhat of a larger background in 16 the area we were interested in. 17 QUESTIONS BY MR. BOWDEN: 18 Q. Right. So they were more 19 qualified for the task at hand? 20 MR. HEGARTY: Objection. Form. 21 MR. DONATH: Objection to form. 22 THE WITNESS: No, they could 23 represent -- they could opine better 24 as to the subject matter of the 25 litigation.</p>	<p>1 strike the narrative. 2 QUESTIONS BY MR. BOWDEN: 3 Q. Go into this document now. 4 And you're with me on .5, 5 right? 6 A. Are you back to the front? 7 Q. No, sir, I'm still on the last 8 page. 9 A. Okay. 10 Q. All right. So at the top 11 there, you see that it's from Robert Glenn. 12 That's you, right? 13 A. Yes. 14 Q. And this is to Michael S., 15 right? 16 A. Yes. 17 Q. And that's actually going to be 18 Dr. Huncharek, right? 19 A. Yes. 20 Q. And he's got 21 metaresearch@hotmail.com, right? 22 A. Yes. 23 Q. Okay. He wasn't asking you to 24 e-mail him at the school. This was part of 25 Meta-Analysis Research Group, right?</p>
Page 115	Page 117
<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. Given the option of 3 Dr. Huncharek and someone else when it came 4 to asbestos, you chose someone else? 5 A. We chose the person that could 6 best represent our client. 7 Q. Oh, I see. 8 And that's separate and 9 distinct from qualifications? 10 MR. DAVANT: Objection. Form. 11 THE WITNESS: We -- I had a 12 role in accepting and in recommending 13 scientists to serve as expert witness. 14 I have a broad group of expert -- 15 of -- not expert, broad group of 16 scientists that I've known through my 17 days at NIOSH and afterwards, and I'm 18 always looking for the best. 19 I did not know Dr. Huncharek 20 personally when I brought his name up. 21 QUESTIONS BY MR. BOWDEN: 22 Q. I think our jury will 23 understand. 24 All right. Let's go -- 25 MR. BILLINGS-KANG: Move to</p>	<p>1 A. He was doing this, as I recall, 2 for his group that he had formed, this 3 Meta-Analysis Research Group. 4 Q. All right. And it says, 5 "Subject, Projects-Huncharek," and then the 6 body reads, "Dr. Huncharek, we would like for 7 you to join us tomorrow after, September 7th, 8 at 1:30 p.m. Eastern, for a telephone 9 conference to discuss the NTP talc listing. 10 We will use Luzenac conference telephone 11 system for this call." 12 Do you see where that's 13 written? 14 A. Yes. 15 Q. Okay. And the rest of this 16 document -- or excuse me, let's go back to 17 the reply, which will be right above that. 18 Dr. Huncharek says, "I look 19 forward to speaking with you," right? 20 A. Yes. 21 Q. And it appears that this 22 document, at least the way it was produced to 23 us, this is a brochure from Meta-Analysis 24 Research Group, right? 25 You can go to the first page</p>

30 (Pages 114 to 117)



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<p style="text-align: right;">Page 118</p> <p>1 to -- and we'll go through it together.</p> <p>2 A. Yeah, that appears to be what</p> <p>3 it is.</p> <p>4 Q. And this was sent in advance of</p> <p>5 that call, I take it?</p> <p>6 A. I gather it was, yes.</p> <p>7 Q. And it was part of the</p> <p>8 discussion as to who they are --</p> <p>9 A. Yeah.</p> <p>10 Q. -- what they do, right?</p> <p>11 A. Right.</p> <p>12 Q. Now, this was after you decided</p> <p>13 not to use them in that asbestos litigation?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. So it says here at the</p> <p>16 very first, "this group was formed in 1996 by</p> <p>17 Michael Huncharek."</p> <p>18 Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. And then halfway down that</p> <p>21 paragraph it says, "The MRG is unique in that</p> <p>22 it transcends the traditional boundaries</p> <p>23 between the academic world and the</p> <p>24 marketplace."</p> <p>25 Do you see that?</p>	<p style="text-align: right;">Page 120</p> <p>1 Q. And so they're going to help,</p> <p>2 quote, decipher complex issues, right? That</p> <p>3 was one of the things that you hired them to</p> <p>4 do?</p> <p>5 A. No, that's what he wrote in</p> <p>6 this.</p> <p>7 Q. Okay.</p> <p>8 A. This was not -- did not affect</p> <p>9 my hiring him. This is boilerplate, and I</p> <p>10 doubt if he even read it, but...</p> <p>11 Q. Who are you talking about?</p> <p>12 A. This document.</p> <p>13 Q. Who was the -- who was the "I</p> <p>14 doubt he even read it"? You think</p> <p>15 Mr. Huncharek didn't read this?</p> <p>16 A. I doubt I read it.</p> <p>17 Q. Okay. Let's turn to the third</p> <p>18 page -- or, excuse me, the second page.</p> <p>19 A. Yes.</p> <p>20 Q. We're going to go to the bottom</p> <p>21 paragraph first. "Medical/scientific</p> <p>22 writing, scientific editing. Report and</p> <p>23 manuscript preparation for internal and</p> <p>24 external applications. Our ability to</p> <p>25 generate manuscripts of publishable quality</p>
<p style="text-align: right;">Page 119</p> <p>1 A. I see that.</p> <p>2 Q. And that was one of the unique</p> <p>3 things they did, was they didn't just look at</p> <p>4 the academic side of it, they also looked at</p> <p>5 the marketplace, the business side of issues,</p> <p>6 correct?</p> <p>7 MR. HEGARTY: Objection. Form.</p> <p>8 MR. DONATH: Objection. Form.</p> <p>9 THE WITNESS: That's his words.</p> <p>10 QUESTIONS BY MR. BOWDEN:</p> <p>11 Q. Okay. Did you ever ask him</p> <p>12 what that meant?</p> <p>13 A. No.</p> <p>14 Q. Okay. Well, let's continue on</p> <p>15 and see what it means.</p> <p>16 A. I didn't focus on that at all.</p> <p>17 Q. Okay. The bottom of this first</p> <p>18 page, the last paragraph: "We have assisted</p> <p>19 major pharmaceutical companies and other</p> <p>20 clients in, quote, deciphering often complex,</p> <p>21 seemingly contradictory data using rigorous</p> <p>22 meta-analytical methods."</p> <p>23 Do you see where that's</p> <p>24 written?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 121</p> <p>1 is unparalleled in the private sector. MRG</p> <p>2 will guide manuscripts through the entire</p> <p>3 editorial process from submission of the</p> <p>4 manuscript to final publication."</p> <p>5 Do you see that where that's</p> <p>6 written?</p> <p>7 A. Yes.</p> <p>8 Q. In fact, that's one of the</p> <p>9 things that you ultimately hired them to do,</p> <p>10 right?</p> <p>11 MR. DONATH: Objection. I'm</p> <p>12 going to direct the witness again</p> <p>13 to -- not to give any answer with</p> <p>14 respect to your work for Imerys at</p> <p>15 Crowell &amp; Moring.</p> <p>16 MR. BOWDEN: That's what you</p> <p>17 hired him to do.</p> <p>18 MR. DONATH: Objection. Same</p> <p>19 direction.</p> <p>20 MR. BOWDEN: Are you telling</p> <p>21 him not to answer this question?</p> <p>22 MR. DONATH: If it'll waive the</p> <p>23 privilege, I am.</p> <p>24 QUESTIONS BY MR. BOWDEN:</p> <p>25 Q. Did you hire them? That's not</p>

31 (Pages 118 to 121)



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<p style="text-align: right;">Page 122</p> <p>1 a privilege question. Did you hire them; yes 2 or no? 3 A. No, I did not. 4 Q. Did Crowell &amp; Moring hire them? 5 That's not a privilege question. Yes or no? 6 A. Yes. 7 Q. Okay. And you hired them after 8 this was sent to you, correct? 9 A. We hired them after we 10 obtained, I believe, a proposal. 11 Q. Right. We're going to get to 12 the proposal next. 13 And that proposal wasn't just 14 to Luzenac, right? You shared it with other 15 people. 16 A. I may have, yes. 17 Q. You shared it with Johnson &amp; 18 Johnson, right? 19 MR. HEGARTY: Objection. Form. 20 THE WITNESS: I don't know if I 21 did. Let's see. 22 QUESTIONS BY MR. BOWDEN: 23 Q. Well, let's just make clear 24 because your counsel keeps pointing out for 25 everyone to hear that they think this is</p>	<p style="text-align: right;">Page 124</p> <p>1 liability. 2 QUESTIONS BY MR. BOWDEN: 3 Q. Right. 4 That's what Crowell &amp; Moring 5 does, too, right? 6 MR. DONATH: Objection to form. 7 THE WITNESS: That's one of the 8 things they do. 9 QUESTIONS BY MR. BOWDEN: 10 Q. Okay. 11 A. They're a full-service firm. 12 Q. "Environment and other 13 medically oriented litigation." 14 A. Yes, that's what it says. 15 Q. "Expert witness"? 16 A. Yes. 17 Q. "Cause for action"? 18 A. Yes. 19 Q. "Medical record review"? 20 A. Yes. 21 Q. In 2004, was it your intent to 22 hire them and groom them as expert witnesses? 23 MR. BILLINGS-KANG: Objection 24 to form. 25 MR. DONATH: Objection to form.</p>
<p style="text-align: right;">Page 123</p> <p>1 privileged. 2 So were you sharing the 3 information you got from Meta-Analysis 4 Research Group with Johnson &amp; Johnson as you 5 were getting it? 6 A. You're asking me about 7 something 14 years ago. If you show me where 8 I did, I will accept that, but I don't -- 9 that was not -- I don't recall doing that. I 10 may have. 11 Q. Okay. We're going to go into 12 that. 13 A. Good. 14 Q. Let's go into the next section 15 first, the one right above that, please. 16 A. Okay. 17 Q. Medical and legal consulting. 18 "High quality consulting services for medical 19 malpractice, toxic tort" -- 20 Toxic tort's a thing like talc, 21 right? 22 MR. DONATH: Objection. Form. 23 MR. HEGARTY: Objection to 24 form. 25 THE WITNESS: It's product</p>	<p style="text-align: right;">Page 125</p> <p>1 THE WITNESS: It was -- we 2 hired them to get reports on the 3 relationship between talc and ovarian 4 cancer, scientific reports. 5 QUESTIONS BY MR. BOWDEN: 6 Q. That doesn't answer my 7 question, though. 8 Was one of the considerations 9 at the time that you hired them the idea that 10 they could ultimately become expert 11 witnesses? 12 A. No, not expert witnesses in 13 litigation. 14 Q. Expert witnesses in what? 15 A. In regulatory affairs. 16 Q. Oh, things like communicating 17 with the NTP or the IARC, right? 18 A. Yes. 19 Q. I see. 20 So you were grooming them for 21 that purpose? 22 MR. DONATH: Objection to form. 23 MR. BILLINGS-KANG: Objection 24 to form. 25 THE WITNESS: We weren't</p>



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<p style="text-align: right;">Page 126</p> <p>1 grooming them.</p> <p>2 QUESTIONS BY MR. BOWDEN:</p> <p>3 Q. Okay. We're going to talk</p> <p>4 about that a little bit later, too.</p> <p>5 All right.</p> <p>6 MR. HEGARTY: Move to strike</p> <p>7 the commentary. No question pending.</p> <p>8 (Glenn Exhibit 11 marked for</p> <p>9 identification.)</p> <p>10 QUESTIONS BY MR. BOWDEN:</p> <p>11 Q. I'm going to hand you what I</p> <p>12 will mark as Exhibit Number 11. There you</p> <p>13 go, sir.</p> <p>14 A. Uh-huh.</p> <p>15 MR. BOWDEN: Counsel, I got</p> <p>16 copies for you.</p> <p>17 QUESTIONS BY MR. BOWDEN:</p> <p>18 Q. You can see this is a facsimile</p> <p>19 back from you. Now we're back in October</p> <p>20 of 2004.</p> <p>21 A. It's to me, yes.</p> <p>22 Q. Oh, I'm sorry, correct.</p> <p>23 It's to you, right? And this</p> <p>24 is from Dr. Huncharek.</p> <p>25 You see it's handwritten --</p>	<p style="text-align: right;">Page 128</p> <p>1 ovarian cancer," right?</p> <p>2 A. Yes.</p> <p>3 Q. And that was the purpose of</p> <p>4 speaking with them, at least in this series</p> <p>5 of communications that we're looking at, is</p> <p>6 to discuss talc and ovarian cancer, right?</p> <p>7 A. It was.</p> <p>8 MR. DONATH: Objection to form.</p> <p>9 MR. HEGARTY: Objection to</p> <p>10 form.</p> <p>11 QUESTIONS BY MR. BOWDEN:</p> <p>12 Q. Let's go to the next paragraph.</p> <p>13 "As previously discussed, this</p> <p>14 work would take the form of two projects.</p> <p>15 The first of these consists of a thorough</p> <p>16 narrative review of the existing</p> <p>17 epidemiological literature, examine the</p> <p>18 possible relationship, if any, between use of</p> <p>19 cosmetic talc and ovarian cancer. We would</p> <p>20 employ our usual methods as outlined in the</p> <p>21 attached budget summary, including thorough</p> <p>22 electronic database researches, supplemented</p> <p>23 by manual searches of existing scientific</p> <p>24 literature. The work product for this</p> <p>25 project will take the form of a narrative</p>
<p style="text-align: right;">Page 127</p> <p>1 A. Yes.</p> <p>2 Q. -- in the "from" line, right?</p> <p>3 A. Yes.</p> <p>4 Q. And then the message says,</p> <p>5 "Agreement." Right?</p> <p>6 A. Yes.</p> <p>7 Q. "Look forward to speaking" -- I</p> <p>8 can't read that. Maybe it means tomorrow or</p> <p>9 something.</p> <p>10 A. Yeah.</p> <p>11 Q. All right. So let's turn to</p> <p>12 the second page.</p> <p>13 A. All right.</p> <p>14 Q. And at the very top it says,</p> <p>15 "To Robert Glenn, Crowell &amp; Moring," and this</p> <p>16 is "regarding talc project's letter of</p> <p>17 agreement."</p> <p>18 A. Yes.</p> <p>19 Q. Do you see where that's</p> <p>20 written?</p> <p>21 A. Yes.</p> <p>22 Q. First paragraph reads, "It's</p> <p>23 been a pleasure speaking with you and your</p> <p>24 colleagues regarding projects related to</p> <p>25 epidemiology of talc and its relationship to</p>	<p style="text-align: right;">Page 129</p> <p>1 summary of our interpretation of the existing</p> <p>2 scientific literature on this topic that will</p> <p>3 be submitted to your firm for review prior to</p> <p>4 possible submission to the NTP."</p> <p>5 Do you see where that's</p> <p>6 written?</p> <p>7 A. Yes.</p> <p>8 Q. So one of the things that</p> <p>9 Crowell &amp; Moring was doing, or you were doing</p> <p>10 on Crowell &amp; Moring's behalf on Luzenac's</p> <p>11 behalf, was contacting them in anticipation</p> <p>12 that a report might need to be submitted to</p> <p>13 the NTP?</p> <p>14 A. Yes.</p> <p>15 MR. DONATH: Objection to form.</p> <p>16 THE WITNESS: Yes, to possibly</p> <p>17 make a submission to the NTP.</p> <p>18 QUESTIONS BY MR. BOWDEN:</p> <p>19 Q. Right. And we're going to talk</p> <p>20 about what actually happened with that in</p> <p>21 just a second.</p> <p>22 Go down two more paragraphs,</p> <p>23 "an additional goal." "An additional goal of</p> <p>24 this project is to create an academic review</p> <p>25 article suitable for submission to a</p>



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<p>1 recognized medical, scientific journal.  2 Prior to submission to an outside journal,  3 our firm and clients are entitled to comment  4 on its content, suggest changes and possible  5 avenues for publication."  6 I'm sorry, "your firm." Let  7 me -- strike that. Let me reread it.  8 "Prior to submission to an  9 outside journal, your firm and clients are  10 entitled to comment on its content, suggest  11 changes and possible avenues for  12 publication."  13 Do you see where that's  14 written?  15 A. Yes, I do.  16 Q. And the next paragraph says,  17 "The second project included in the terms of  18 our agreement is a meta-analysis examining  19 the possible association of cosmetic talc use  20 with contraceptive diaphragms and the risk of  21 cancer of the ovary."  22 Do you see where that is?  23 A. Yes.  24 Q. And in regards to that project,  25 Crowell &amp; Moring actually retained the right</p>	<p>1 cancer?  2 MR. BILLINGS-KANG: Objection  3 to form.  4 MR. DONATH: Objection to form.  5 THE WITNESS: No, that was not  6 our interest. We wanted them to  7 review critically the literature  8 related to talc exposure and ovarian  9 cancer.  10 QUESTIONS BY MR. BOWDEN:  11 Q. Right.  12 And to prepare a report --  13 A. Prepare a report --  14 Q. -- with their findings, their  15 conclusions from their review, right?  16 A. Yes, prepare a report --  17 Q. And --  18 A. -- that might be submitted to  19 the medical literature.  20 Q. That might be submitted, right?  21 A. Yes. That was secondary.  22 Q. But it would be secondary  23 subject to Crowell &amp; Moring's approval?  24 MR. HEGARTY: Objection to  25 form.</p>
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<p>1 to make comments and edits to it prior to  2 submission for publication as well, right?  3 MR. DONATH: Objection.  4 THE WITNESS: That's what he  5 placed in this agreement, yes.  6 QUESTIONS BY MR. BOWDEN:  7 Q. Okay.  8 A. And we accepted the agreement,  9 as I recall.  10 Q. Was that a requirement by you?  11 A. No.  12 Q. That was just what they  13 proposed in the brochure what they could do  14 for you, right?  15 A. Yes.  16 Q. Okay. And ultimately you  17 agreed to hire their services for those two  18 specific tasks that we just covered, right?  19 MR. HEGARTY: Objection. Form.  20 THE WITNESS: Yes.  21 QUESTIONS BY MR. BOWDEN:  22 Q. And the expectation at the time  23 was that their review of the epidemiology  24 data was going to show that there was no  25 causal relationship between talc and ovarian</p>	<p>1 MR. DONATH: Objection to form.  2 MR. BILLINGS-KANG: Objection  3 to form.  4 THE WITNESS: No. The  5 manuscript we had nothing to do with.  6 QUESTIONS BY MR. BOWDEN:  7 Q. You had nothing to do with the  8 manuscript for the critical review?  9 A. To my knowledge, we did not  10 have anything to do, other than review it for  11 technical accuracy and such.  12 We did review the reports and  13 make some comments on the reports, but I  14 don't recall making any comments on the  15 manuscript that went to the journals.  16 (Glenn Exhibit 12 marked for  17 identification.)  18 QUESTIONS BY MR. BOWDEN:  19 Q. Okay. I'm going to hand you  20 what I'm marking as Exhibit Number 12.  21 Did you review this document  22 when you were prepping for deposition?  23 A. I -- yeah, may have. I don't  24 recall exactly whether this is one I reviewed  25 or not.</p>

34 (Pages 130 to 133)



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<p>1 Q. Okay. Well, I think we can go 2 through it pretty quickly. Maybe we should 3 talk about it on a high level, all right? 4 A. Okay. 5 Q. This, for the record, is going 6 to be P1.0039. That's our internal coding. 7 This is cosmetic talc conference call 8 minutes. 9 Do you see that? 10 A. Yes. 11 Q. It says, "A J&amp;J Luzenac 12 teleconference was conducted October 13, 13 2004, to review issues regarding the NTP 14 cosmetic talc nomination for the 12th Report 15 on Carcinogens," what I've been calling the 16 12 ROC, right? 17 A. Yes. 18 Q. "Participants: J&amp;J list, Eric 19 Turner" -- 20 He's with Luzenac, right? 21 A. Yes. 22 Q. -- "and Rich Zazenski," right? 23 A. Yes. 24 Q. Okay. And so as you're talking 25 to Meta-Analysis Research Group, looking at</p>	<p>1 Johnson &amp; Johnson and you, they're looking at 2 two studies, right? The studies that we went 3 over, the Mills paper as well. 4 Do you see that there? 5 MR. DONATH: Objection. Form. 6 MR. HEGARTY: Objection to 7 form. 8 MR. BOWDEN: It's misspelled. 9 It's M-o-l-l-s, but it's M-i. 10 THE WITNESS: Yeah, they have 11 two papers listed. 12 QUESTIONS BY MR. BOWDEN: 13 Q. Okay. 14 A. The 2003 publication is what 15 drew my attention to Dr. Huncharek. 16 Q. Right. 17 And it says, "Dr. Huncharek had 18 previously been contacted by the CTFA and 19 tentatively agreed to present comments at the 20 12th ROC committee sub meeting regarding the 21 lack of observational data to support a 22 causal relationship between perineal talc use 23 and an increased risk of ovarian cancer." 24 Do you see that? 25 A. Yes, I see that.</p>
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<p>1 their proposals, signing the agreement, 2 Johnson &amp; Johnson is involved, true? 3 MR. HEGARTY: Objection. Form. 4 THE WITNESS: Yes, they appear 5 to be involved. I had little contact 6 with J&amp;J, in fact. 7 QUESTIONS BY MR. BOWDEN: 8 Q. So if you go down to the 9 epidemiological studies section, please. 10 We're looking at the very top 11 of this. You'll recall that this was review 12 of issues regarding NTP in the 12th report, 13 right? 14 A. Yes. 15 Q. And we've already looked at the 16 CTFA minutes, right, that were talking about 17 what new science has come out, right? 18 A. Yes. 19 Q. And during those minutes, all 20 they mentioned was Huncharek's paper, right, 21 the 2003 Huncharek paper? 22 A. I suppose. I'd have to go back 23 on that. 24 Q. But when the internal 25 discussion is taking place between Imerys and</p>	<p>1 Q. So you understand that's 2 different than what we had just discussed. 3 Do you see the distinction? 4 A. Yes. 5 MR. HEGARTY: Objection to 6 form. 7 QUESTIONS BY MR. BOWDEN: 8 Q. You just told our jury -- 9 A. Yes. 10 Q. -- that they were contacted to 11 conduct a review and that you weren't 12 expecting an outcome one way or another. 13 Am I saying that correctly? 14 A. That's what we -- 15 Q. But the CTFA, in these internal 16 minutes here, they're saying they were 17 tentatively agreed to support -- to support a 18 report regarding the lack of data with a 19 causal relationship between perineal talc use 20 and increased risk of ovarian cancer. 21 Do you see where that's 22 written? 23 A. That's right. 24 MR. HEGARTY: Objection. 25 MR. DONATH: Objection.</p>

35 (Pages 134 to 137)



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<p>1 Mischaracterizes the testimony because</p> <p>2 this documents doesn't reflect</p> <p>3 anything that Mr. Glenn says in this</p> <p>4 document.</p> <p>5 MR. TISI: Yeah, we can -- we</p> <p>6 can really -- I mean, I'm going to</p> <p>7 stay away, but you're violating the</p> <p>8 rules all over the place. "It's</p> <p>9 objection, form," or "objection, don't</p> <p>10 answer."</p> <p>11 If you're going to keep doing</p> <p>12 that kind of objection, we're going to</p> <p>13 call Judge Pisano.</p> <p>14 MR. DONATH: That's fine,</p> <p>15 Counsel. I understand the rules.</p> <p>16 MR. TISI: Okay. Well, you're</p> <p>17 not obeying them, so let's obey them.</p> <p>18 It's "objection, form," or "objection,</p> <p>19 I instruct the witness not to answer,"</p> <p>20 period.</p> <p>21 QUESTIONS BY MR. BOWDEN:</p> <p>22 Q. All right.</p> <p>23 A. I was -- I was not --</p> <p>24 Q. There's no question pending,</p> <p>25 sir. We're going to set that down.</p>	<p>1 Q. Okay. If anyone was to suggest</p> <p>2 that he was a loose cannon and didn't speak</p> <p>3 for Imerys, would that be true?</p> <p>4 MR. DONATH: Objection to form.</p> <p>5 THE WITNESS: No. He was at</p> <p>6 the time employed by Luzenac, so I</p> <p>7 don't know whether he could be</p> <p>8 speaking for Imerys when he was</p> <p>9 employed by Luzenac.</p> <p>10 QUESTIONS BY MR. BOWDEN:</p> <p>11 Q. I'm not going to play word</p> <p>12 games with you, sir. We've already talked</p> <p>13 about at the beginning of this, Luzenac,</p> <p>14 Rio Tinto, Imerys, I'm referring all to the</p> <p>15 same entity.</p> <p>16 You understand that, right?</p> <p>17 A. The client I worked with was</p> <p>18 Luzenac.</p> <p>19 MR. DONATH: Objection.</p> <p>20 QUESTIONS BY MR. BOWDEN:</p> <p>21 Q. Okay. Was that your experience</p> <p>22 with Mr. Zazenski?</p> <p>23 A. That he was a loose cannon?</p> <p>24 Q. Right.</p> <p>25 A. I don't know if I'd consider</p>
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<p>1 A. There has been one about this.</p> <p>2 Q. No, sir, there's not, actually.</p> <p>3 A. I'm not on this --</p> <p>4 Q. Sir, this is not an opportunity</p> <p>5 for you to speak. You have to answer the</p> <p>6 questions I ask. I know it's not fair, but</p> <p>7 that's how these things work. Okay?</p> <p>8 Hold on to that.</p> <p>9 A. Crowell &amp; Moring didn't ask for</p> <p>10 this --</p> <p>11 Q. Sir, we're not going to go</p> <p>12 through this right now. There's no question</p> <p>13 pending. You can set that aside. Thank you.</p> <p>14 Rich Zazenski. Do you know</p> <p>15 what his function was at Imerys?</p> <p>16 A. I believe he was responsible</p> <p>17 for the safety and health program at Imerys.</p> <p>18 Q. Is he a mineralogist?</p> <p>19 A. No, he has knowledge of</p> <p>20 mineralogy.</p> <p>21 Q. Okay. Was he the primary</p> <p>22 contact point for Imerys on the issue of talc</p> <p>23 and ovarian cancer?</p> <p>24 A. I believe he would be</p> <p>25 considered that, yes.</p>	<p>1 him a loose cannon.</p> <p>2 Q. You would not, would you?</p> <p>3 A. No.</p> <p>4 Q. I assure you I'm trying to keep</p> <p>5 it shorter, so I'm cutting through some</p> <p>6 documents. Just bear with me here.</p> <p>7 A. That's fine.</p> <p>8 Q. Now, you told me a little bit</p> <p>9 about Dr. Huncharek and how you first came</p> <p>10 into contact with him.</p> <p>11 Now I want to ask you: His</p> <p>12 partner, his colleague at MRG that you dealt</p> <p>13 with on this talc and ovarian cancer issue,</p> <p>14 that was Dr. Joshua Muscat, correct?</p> <p>15 MR. HEGARTY: Objection to</p> <p>16 form.</p> <p>17 THE WITNESS: I'm not sure,</p> <p>18 Dr. Muscat, what his relationship with</p> <p>19 Dr. Huncharek's group was or whether</p> <p>20 he was just acting on his own through</p> <p>21 Dr. Huncharek, but -- I don't know</p> <p>22 whether he was considered a group</p> <p>23 member, but Dr. Huncharek brought</p> <p>24 Dr. Muscat to my attention.</p> <p>25</p>



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<p style="text-align: right;">Page 142</p> <p>1 QUESTIONS BY MR. BOWDEN: 2 Q. And when he brought it to your 3 attention, you made sure that Dr. Muscat was 4 on the retainer agreement that Crowell &amp; 5 Moring ultimately signed, right? 6 MR. DAVANT: Objection. Form. 7 THE WITNESS: I think -- I 8 think there was a discussion of 9 whether Crowell &amp; Moring would pay 10 Dr. Muscat or whether it would go 11 through the -- Dr. Huncharek's group. 12 And I think in the end it went through 13 Dr. Huncharek's group. 14 QUESTIONS BY MR. BOWDEN: 15 Q. And I appreciate that, sir, I 16 do, but my question is whether or not you 17 made sure that he was on the retainer 18 agreement with Crowell &amp; Moring and MRG. 19 MR. HEGARTY: Objection. Form. 20 MR. DONATH: Objection to form. 21 THE WITNESS: That was the 22 question of Dr. Huncharek, and we went 23 along with it. 24 QUESTIONS BY MR. BOWDEN: 25 Q. You went along with it to make</p>	<p style="text-align: right;">Page 144</p> <p>1 THE WITNESS: Okay. 2 QUESTIONS BY MR. BOWDEN: 3 Q. Who added that term? 4 A. Who what? 5 Q. Who added the confidentiality 6 term? 7 A. It's in a communication from 8 Mr. Hall. 9 Q. Mr. Hall added the term? 10 MR. DAVANT: Object to form. 11 THE WITNESS: He is the one 12 that's -- in his communication put 13 that in, so I suppose. 14 QUESTIONS BY MR. BOWDEN: 15 Q. So I'd asked you a little bit 16 before about some of the involvement of 17 Johnson &amp; Johnson, whether they were involved 18 from the get-go with MRG. 19 You understood at the time that 20 these proposals were being sent back and 21 forth -- 22 A. I did. 23 MR. HEGARTY: Objection. Form. 24 MR. DONATH: Objection to form. 25</p>
<p style="text-align: right;">Page 143</p> <p>1 sure he was a retained member of MRG and 2 consulting for these two top -- these two 3 tasks, the NTP report and the diaphragm -- 4 A. Study. 5 Q. -- study. 6 MR. DONATH: Objection to form. 7 MR. HEGARTY: Objection. Form. 8 THE WITNESS: Yeah, consultant. 9 Yes. 10 QUESTIONS BY MR. BOWDEN: 11 Q. And part of that was that you 12 wanted to make sure that he was subject to a 13 confidentiality agreement, true? 14 MR. HEGARTY: Objection. Form. 15 THE WITNESS: That wasn't my 16 role, but there was language related 17 to that in communications from 18 Mr. Hall. 19 QUESTIONS BY MR. BOWDEN: 20 Q. Mr. Hall made sure that you had 21 him underneath the confidentiality, right? 22 A. No, he -- 23 MR. DONATH: Objection. Direct 24 the witness not to answer with respect 25 to anything Mr. Hall told you.</p>	<p style="text-align: right;">Page 145</p> <p>1 QUESTIONS BY MR. BOWDEN: 2 Q. -- that Johnson &amp; Johnson was 3 going to be paying for half the cost, right? 4 MR. HEGARTY: Objection to 5 form. 6 THE WITNESS: That later came 7 up, yes. 8 QUESTIONS BY MR. BOWDEN: 9 Q. And Johnson &amp; Johnson at that 10 time or afterwards, from the time that you 11 were at Crowell &amp; Moring, never were they a 12 client of yours, of Crowell &amp; Moring law 13 firm? 14 A. I don't think they had any 15 matters being litigated or being -- 16 Q. Well, we saw in your response 17 to the notice of deposition that the only 18 client was Luzenac, right? 19 A. Yes, they were the client on 20 this matter. 21 Q. Not Johnson &amp; Johnson? 22 A. No. 23 Q. Okay. But they were involved 24 in it and they were paying for it, right? 25 MR. HEGARTY: Objection. Form.</p>

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<p>1 THE WITNESS: Yes.</p> <p>2 QUESTIONS BY MR. BOWDEN:</p> <p>3 Q. They were on the conference</p> <p>4 calls?</p> <p>5 A. Yes.</p> <p>6 MR. HEGARTY: Objection. Form.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. They were participants in the</p> <p>9 formation of the agreements?</p> <p>10 MR. HEGARTY: Objection. Form.</p> <p>11 THE WITNESS: I don't know if</p> <p>12 they came in late or after the</p> <p>13 agreements were being discussed, but I</p> <p>14 think they did have -- they did look</p> <p>15 at the agreements before we engaged</p> <p>16 Dr. Huncharek and his firm.</p> <p>17 QUESTIONS BY MR. BOWDEN:</p> <p>18 Q. Does Meta-Analysis Research</p> <p>19 Group only work for law firms?</p> <p>20 A. I do not know.</p> <p>21 Q. Did you ever ask?</p> <p>22 A. I didn't have any reason to</p> <p>23 ask.</p> <p>24 Q. Didn't matter to your analysis?</p> <p>25 MR. BILLINGS-KANG: Objection.</p>	<p>1 Mr. Hall.</p> <p>2 QUESTIONS BY MR. BOWDEN:</p> <p>3 Q. Is that your understanding?</p> <p>4 A. That's my understanding.</p> <p>5 (Glenn Exhibit 13 marked for</p> <p>6 identification.)</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. I'm going to hand you what I am</p> <p>9 marking as Exhibit Number 13.</p> <p>10 A. If we could take a break in</p> <p>11 about ten minutes?</p> <p>12 Q. I tell you what, why don't we</p> <p>13 go through this document and then we'll take</p> <p>14 a break. That'd be just fine.</p> <p>15 A. That's fine. Nature calls.</p> <p>16 Q. Are you okay with waiting?</p> <p>17 A. Yeah. Yeah.</p> <p>18 Q. Let's start off at the bottom</p> <p>19 of this e-mail.</p> <p>20 A. Okay.</p> <p>21 Q. This is a e-mail from Ridgway</p> <p>22 Hall, the attorney at Crowell &amp; Moring,</p> <p>23 right?</p> <p>24 A. Yes.</p> <p>25 Q. It's to Steven Mann at Johnson</p>
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<p>1 Form.</p> <p>2 THE WITNESS: I didn't have any</p> <p>3 reason to ask. I was hiring them to</p> <p>4 do a scientific -- that's what I was</p> <p>5 concerned with, is the scientific</p> <p>6 conventions.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. At some point Johnson &amp; Johnson</p> <p>9 expressed concern over being included on the</p> <p>10 agreement, right?</p> <p>11 MR. BILLINGS-KANG: Objection.</p> <p>12 Form.</p> <p>13 THE WITNESS: Yes, they did.</p> <p>14 QUESTIONS BY MR. BOWDEN:</p> <p>15 Q. They understood, based on your</p> <p>16 discussions with Mr. Mann and others, that</p> <p>17 the science was going to run through</p> <p>18 Crowell &amp; Moring and through MRG, right?</p> <p>19 MR. HEGARTY: Objection. Form.</p> <p>20 MR. DONATH: Objection to form.</p> <p>21 MR. BILLINGS-KANG: Objection</p> <p>22 to form.</p> <p>23 THE WITNESS: It wasn't</p> <p>24 discussions I had with Mr. Mann</p> <p>25 related to that. It took place with</p>	<p>1 &amp; Johnson?</p> <p>2 A. Right.</p> <p>3 Q. And it copies Mr. Zazenski?</p> <p>4 A. Yes.</p> <p>5 Q. Ralph Godell? Is that how you</p> <p>6 say his name?</p> <p>7 A. Godell.</p> <p>8 Q. Godell.</p> <p>9 He's also with Luzenac, right?</p> <p>10 A. Yes.</p> <p>11 Q. And you?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. And that e-mail says,</p> <p>14 "Dear Steve, we'd like to get Drs. Huncharek</p> <p>15 and Muscat started as soon as possible on the</p> <p>16 studies we have been discussing."</p> <p>17 And that Steve would be --</p> <p>18 that's Steve Mann at Johnson &amp; Johnson,</p> <p>19 right?</p> <p>20 A. Yes.</p> <p>21 Q. "Please let me know at your</p> <p>22 earliest convenience whether J&amp;J would like</p> <p>23 its name on the retainer letter or not and</p> <p>24 whether J&amp;J would like to share with Luzenac</p> <p>25 the cost of the second task."</p>

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<p>1 The second task was the</p> <p>2 diaphragm study, right?</p> <p>3 A. Yes.</p> <p>4 Q. "We understand that you are on</p> <p>5 board to split evenly the cost of the first.</p> <p>6 Many thanks. Regards, Ridge," right?</p> <p>7 A. Right.</p> <p>8 Q. And the response back, we go</p> <p>9 back up to the top. "Ridge, in talking to my</p> <p>10 boss, I think it would be better if J&amp;J was</p> <p>11 not mentioned in the retainer letter. I</p> <p>12 don't yet have a definitive answer on</p> <p>13 splitting the cost of the second study yet,</p> <p>14 but that shouldn't hold you up from</p> <p>15 proceeding with Mike and Josh."</p> <p>16 That's Huncharek and Muscat,</p> <p>17 right?</p> <p>18 MR. HEGARTY: Objection to</p> <p>19 form.</p> <p>20 THE WITNESS: Yes.</p> <p>21 QUESTIONS BY MR. BOWDEN:</p> <p>22 Q. "However, it will be my</p> <p>23 recommendation that Josh" --</p> <p>24 Josh Muscat, right?</p> <p>25 A. Yes.</p>	<p>1 Group, the outcome of the diaphragm study was</p> <p>2 discussed prior to funding, true?</p> <p>3 MR. HEGARTY: Objection to</p> <p>4 form.</p> <p>5 THE WITNESS: I don't recall</p> <p>6 that I was ever involved in those</p> <p>7 conversations. In this document I</p> <p>8 have not seen -- I don't know if it</p> <p>9 was in the documents I looked at to</p> <p>10 prepare for the deposition, but I</p> <p>11 don't recall seeing this. Maybe I</p> <p>12 did, but I wasn't involved in this</p> <p>13 discussion.</p> <p>14 QUESTIONS BY MR. BOWDEN:</p> <p>15 Q. Okay. I understand that you</p> <p>16 weren't involved in this e-mail here, but the</p> <p>17 conversations with Muscat and with you and</p> <p>18 with Zazenski and Hall, was it ever discussed</p> <p>19 what the expected outcome of the diaphragm</p> <p>20 study would be?</p> <p>21 MR. DONATH: Objection. Direct</p> <p>22 the witness not to answer.</p> <p>23 QUESTIONS BY MR. BOWDEN:</p> <p>24 Q. And Johnson &amp; Johnson.</p> <p>25 A. Yeah. I don't recall being</p>
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<p>1 Q. -- "expects favorable results</p> <p>2 from the diaphragm/ovarian comparison; thus,</p> <p>3 we should be willing to support that study</p> <p>4 also."</p> <p>5 Do you see where that's</p> <p>6 written?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. So during the conference</p> <p>9 calls that you were part of with Johnson &amp;</p> <p>10 Johnson and Luzenac and the MRG research</p> <p>11 group, the expected conclusions were</p> <p>12 discussed as well, right?</p> <p>13 MR. DONATH: Objection. Direct</p> <p>14 the witness not to answer with respect</p> <p>15 to any discussions with Imerys that</p> <p>16 are not reflected in this document.</p> <p>17 MR. BOWDEN: That Johnson &amp;</p> <p>18 Johnson is a party to? Is that what</p> <p>19 you're telling him?</p> <p>20 MR. DONATH: With Imerys.</p> <p>21 QUESTIONS BY MR. BOWDEN:</p> <p>22 Q. Okay. Let me rephrase it.</p> <p>23 On the conference calls that</p> <p>24 you're involved with at the time with members</p> <p>25 from Luzenac, Johnson &amp; Johnson and the MRG</p>	<p>1 involved in that, but -- I just don't</p> <p>2 remember being involved in those discussions</p> <p>3 myself. I think it's --</p> <p>4 Q. Let me ask you a different way.</p> <p>5 I'm sorry, go ahead.</p> <p>6 A. Yeah. I'd read the literature</p> <p>7 pretty completely, reviews -- review papers</p> <p>8 and such, and I had formed my opinion about</p> <p>9 the scientific evidence relating to talc</p> <p>10 exposure through perineal dusting and ovarian</p> <p>11 cancer, and my conclusion was the evidence</p> <p>12 was weak. On balance, the scientific</p> <p>13 evidence was weak.</p> <p>14 Q. Okay.</p> <p>15 A. And as I -- as I said earlier</p> <p>16 about studies I've been involved in, I</p> <p>17 sometimes go in with them with a scientific</p> <p>18 opinion of more or less -- more or less an</p> <p>19 opinion I've had. And I've been wrong</p> <p>20 once -- once I've been involved in research</p> <p>21 of that nature.</p> <p>22 Q. Would it be appropriate -- as a</p> <p>23 published author yourself, would it be</p> <p>24 appropriate to approach a party to fund a</p> <p>25 scientific study and say that you expect an</p>

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<p style="text-align: right;">Page 154</p> <p>1 outcome?</p> <p>2 MR. DONATH: Objection to form.</p> <p>3 MR. BILLINGS-KANG: Objection</p> <p>4 to form.</p> <p>5 THE WITNESS: No, I wouldn't --</p> <p>6 I don't think I've ever done that.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. That would be inappropriate?</p> <p>9 A. That would be inappropriate.</p> <p>10 MR. DONATH: Objection. Form.</p> <p>11 MR. BOWDEN: I'm sorry, you</p> <p>12 asked for a break. Let's take a</p> <p>13 break.</p> <p>14 THE WITNESS: Yes, if you don't</p> <p>15 mind.</p> <p>16 VIDEOGRAPHER: The time is now</p> <p>17 10:54. Going off the record.</p> <p>18 (Off the record at 10:54 a.m.)</p> <p>19 VIDEOGRAPHER: The time is now</p> <p>20 11:09 -- I'm sorry, 11:10. Back on</p> <p>21 the record.</p> <p>22 (Glenn Exhibit 14 marked for</p> <p>23 identification.)</p> <p>24 QUESTIONS BY MR. BOWDEN:</p> <p>25 Q. All right. Mr. Glenn, I'm</p>	<p style="text-align: right;">Page 156</p> <p>1 A. Yes.</p> <p>2 Q. "Signed copies along with</p> <p>3 Attachment A are on the way to each of you by</p> <p>4 snail mail. When I receive the executed</p> <p>5 letters back, we'll owe Dr. Huncharek's</p> <p>6 group, Meta-Analysis Research Group, the</p> <p>7 first installment of 13,950, one-third of the</p> <p>8 total. To maximize the effectiveness of our</p> <p>9 use of the attorney product privilege for</p> <p>10 their work, I will plan to send them a</p> <p>11 Crowell &amp; Moring check in that amount to be</p> <p>12 reimbursed to us by Luzenac and Johnson &amp;</p> <p>13 Johnson in whatever proportions you agree</p> <p>14 on."</p> <p>15 Do you see where that's</p> <p>16 written?</p> <p>17 A. Yes.</p> <p>18 Q. And just again, to clarify now,</p> <p>19 at this point in time Johnson &amp; Johnson is</p> <p>20 still not a client of Crowell &amp; Moring,</p> <p>21 correct?</p> <p>22 MR. HEGARTY: Objection to</p> <p>23 form.</p> <p>24 THE WITNESS: Correct.</p> <p>25</p>
<p style="text-align: right;">Page 155</p> <p>1 going to hand you Exhibit Number 14.</p> <p>2 All right. Mr. Glenn, I'm</p> <p>3 handing you what I'm marking as Exhibit 14.</p> <p>4 MR. BOWDEN: And Mr. Smith,</p> <p>5 that'll be P1.0042.</p> <p>6 MR. SMITH: Yeah. Great.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. This is an e-mail from Ridgway</p> <p>9 Hall to Rich Zazenski, Steven Mann, and also</p> <p>10 copies you.</p> <p>11 Do you see where that is?</p> <p>12 A. Yes.</p> <p>13 Q. And this is now February 28,</p> <p>14 2005.</p> <p>15 Do you see that?</p> <p>16 A. Yes.</p> <p>17 Q. And Ridgway Hall writes -- the</p> <p>18 lawyer, Ridgway Hall, writes, "Dear</p> <p>19 colleagues, the retainer letter is going out</p> <p>20 today in final form for execution by</p> <p>21 Drs. Huncharek and Muscat. Attached for your</p> <p>22 info are the transmittal letter and the</p> <p>23 retainer letter."</p> <p>24 Do you see where that's</p> <p>25 written?</p>	<p style="text-align: right;">Page 157</p> <p>1 QUESTIONS BY MR. BOWDEN:</p> <p>2 Q. Now, at this time period, aside</p> <p>3 from the agreement itself, was the majority</p> <p>4 of the communication going through you to</p> <p>5 Meta-Analysis Research Group?</p> <p>6 A. No, I think mainly what I would</p> <p>7 communicate with was related to the science.</p> <p>8 This business aspect was handled by Mr. Hall.</p> <p>9 Q. Okay. So Mr. Hall was the</p> <p>10 business side of the law firm's interactions</p> <p>11 and you were the science side?</p> <p>12 A. That's pretty much --</p> <p>13 Q. Is that a fair way of saying</p> <p>14 it?</p> <p>15 A. That's a pretty fair way of</p> <p>16 saying it.</p> <p>17 Q. Okay. And the purpose being</p> <p>18 expressed here of the payment going through</p> <p>19 Crowell &amp; Moring is to try to protect -- to</p> <p>20 keep a privilege on the work, right?</p> <p>21 MR. HEGARTY: Objection to</p> <p>22 form.</p> <p>23 THE WITNESS: I think it's</p> <p>24 practice in firms that generally when</p> <p>25 you're working with a client, that</p>

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<p>1 information is considered privileged, 2 yes. 3 QUESTIONS BY MR. BOWDEN: 4 Q. Okay. Information about who is 5 funding the study? 6 MR. HEGARTY: Objection. Form. 7 QUESTIONS BY MR. BOWDEN: 8 Q. Is that a common practice? 9 A. I'm not an attorney. I thought 10 most all communications were -- there was a 11 protection to them. 12 Q. No, no, no, that's not my 13 question. 14 We just established that you're 15 on the science side of it -- 16 A. Yeah. 17 Q. -- and you yourself are a 18 published author, and we've already talked a 19 little bit about funding generally. 20 My question to you is, should 21 the source of funding be kept confidential 22 and private for a paper that's ultimately 23 published? 24 MR. HEGARTY: Objection. Form. 25 THE WITNESS: Not -- no, it</p>	<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. And that's an important 3 consideration, right? 4 A. It can be. 5 Q. And it could be an important 6 consideration in weighing the veracity of the 7 conclusions, right? 8 MR. HEGARTY: Objection. Form. 9 MR. DONATH: Objection to form. 10 THE WITNESS: Not in my opinion 11 as a scientist. 12 QUESTIONS BY MR. BOWDEN: 13 Q. Okay. But you do feel that it 14 would be inappropriate to hide the source of 15 fundings, correct? 16 A. Yes. Certainly from the -- I 17 mean, from the journal, that's when usually 18 the acknowledgement is -- comes related to 19 the source of funding. 20 Q. And beyond just journal 21 publications, interacting with regulatory 22 bodies, many, if not all of those, require 23 financial disclosures, right -- 24 MR. HEGARTY: Objection. Form. 25</p>
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<p>1 shouldn't at the end of the work, 2 certainly. 3 QUESTIONS BY MR. BOWDEN: 4 Q. Right. 5 Because that would be 6 inappropriate, right? 7 A. Yes. 8 MR. DONATH: Objection to form. 9 QUESTIONS BY MR. BOWDEN: 10 Q. That would mask biases 11 potentially in the paper, right? 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: No, I don't think 15 it masked biases necessarily. 16 QUESTIONS BY MR. BOWDEN: 17 Q. Okay. Well, you would agree 18 with me that it would deprive the reader of 19 an article from assessing whether the author 20 had a bias, right? 21 MR. DONATH: Objection. Form. 22 THE WITNESS: Well, I don't 23 know about assessing bias. It 24 wouldn't inform the reader of who paid 25 for the work.</p>	<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. -- if you're going to be 3 speaking before a regulatory body? 4 MR. HEGARTY: Objection. Form. 5 THE WITNESS: I don't -- I 6 don't know if -- that may have taken 7 place at the OSHA hearing, and that 8 might be the first place I saw that 9 take place, and that was just four 10 years ago or so, three, four. 11 QUESTIONS BY MR. BOWDEN: 12 Q. Four years ago. Okay. 13 Does NTP require disclosure of 14 financial interest? 15 A. I don't know if they do now. 16 They didn't -- I don't think it was ever that 17 during the period they were handling the NTP 18 process. 19 Certainly in NIOSH, when I was 20 in NIOSH, people appeared before NIOSH to 21 state opinion, provide information. That was 22 not required. 23 Q. How about IARC proceedings? 24 A. I don't know what IARC requires 25 for their working group members.</p>

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<p style="text-align: right;">Page 162</p> <p>1 Q. I'm not talking about working 2 group members. I mean people who are going 3 to appear to either observe or give 4 testimony. 5 MR. HEGARTY: Objection to 6 form. 7 THE WITNESS: Well, observers 8 are nominated by industry groups, so, 9 yes, they know that. Excuse me. 10 (Glenn Exhibit 15 marked for 11 identification.) 12 QUESTIONS BY MR. BOWDEN: 13 Q. I'm going to hand you what I'm 14 marking now as Exhibit Number 15, P1.37. 15 Actually, let's go back to 16 P149, please. I'm trying to save myself 17 time, and it ended up costing me. 18 This is going to be Exhibit 19 Number 15. P1.0035. 20 Now we're going forward in 21 time. You see we're up to now May of 2005. 22 Do you see that? 23 A. Yes. 24 Q. And this is a call between -- 25 actually, it's an e-mail from you to the</p>	<p style="text-align: right;">Page 164</p> <p>1 It didn't specify reports, but that's 2 the way it worked out, as I recall. 3 QUESTIONS BY MR. BOWDEN: 4 Q. Yeah, and there was only tasks 5 they were being asked to deliver. 6 A. They were at that time. 7 Q. One was the diaphragm study. 8 A. Yes. 9 Q. The other was an NTP report, 10 right? 11 A. Right. 12 MR. HEGARTY: Objection. Form. 13 QUESTIONS BY MR. BOWDEN: 14 Q. And on this e-mail -- 15 MR. BOWDEN: I want to go down, 16 Mr. Smith, down to primary purpose. 17 QUESTIONS BY MR. BOWDEN: 18 Q. The primary purpose of the call 19 that you're setting up in this e-mail was to 20 have Dr. Huncharek and Muscat update you on 21 the progress related to the literature review 22 regarding the use of talc as a perineal 23 dusting agent and its relationship with 24 ovarian cancer, and to update us on the 25 progress of the meta-analysis study of talc</p>
<p style="text-align: right;">Page 163</p> <p>1 Meta-Analysis Research Group, Muscat, 2 Zazenski, and Steven Mann. 3 Do you see that? 4 A. Yes. 5 Q. And it says, "Attachments, talc 6 is a sclerosing" -- I think that's 7 misspelled, agent, but that's what it's 8 supposed to be, right? 9 A. Yes. Okay. 10 Q. -- "and sclerosing strategy 11 attachments." 12 Do you see that there? 13 A. Yes. 14 Q. Now, we had seen a little bit 15 ago, at the beginning of your deposition, 16 where one of the terms of the agreement was 17 that Crowell &amp; Moring as well as the clients, 18 Luzenac -- and we've seen Johnson &amp; Johnson 19 played a role, too -- had a right to comment, 20 to edit and propose their suggestions to the 21 authors, right? 22 MR. HEGARTY: Objection to 23 form. 24 THE WITNESS: To the authors. 25 And as I recall, that was for reports.</p>	<p style="text-align: right;">Page 165</p> <p>1 and ovarian cancer. 2 That would be the diaphragm 3 study, right? 4 A. Yes. 5 Q. Okay. So again, we're just 6 talking about the two deliverables that we've 7 gone through the agreements on, right? 8 A. Those were the primary 9 purposes, yes. 10 Q. And then there's a secondary 11 purpose of the call. 12 Do you see the next paragraph 13 down there? 14 A. Yes. 15 Q. Would be to discuss the 16 experience with talc use as a sclerosing 17 agent, the likelihood talc use and perineal 18 dusting migration to the ovary, and three, 19 the study of perineal talc exposure and 20 ovarian cancer in the Central Valley of 21 California. 22 A. Yes. 23 Q. And that Central Valley 24 California, that's the Mills paper, right? 25 A. Yes.</p>

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Robert Glenn

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<p>1 Q. Okay. "Firstly, you will find 2 attached a strategy that discusses how the 3 experience of talc being used as a sclerosing 4 agent could possibly be used to discount its 5 role as a factor in ovarian cancer." 6 Right? 7 A. That's correct. 8 Q. And that actual strategy came 9 from you? 10 A. Yes, it did. 11 Q. Were you the author of the 12 strategy? 13 A. Yes. 14 Q. Okay. Let's look at the 15 strategy itself. 16 A. All right. 17 MR. BOWDEN: Corey, let's go 18 ahead and turn to page 7, 35.7, 19 please. 20 THE WITNESS: Okay. 21 QUESTIONS BY MR. BOWDEN: 22 Q. You with me on this, sir, the 23 hypothesis section? 24 A. Yes. 25 Q. Okay. "Hypothesis of why talc</p>	<p>1 Q. Go ahead, I'll let you. 2 A. -- understand what -- this is 3 something that formed my opinion -- 4 Q. Okay. 5 A. -- about talc not being an 6 ovarian carcinogen, the experience with using 7 5 grams and above on the pleural tissue to 8 cause adhesions to prevent spontaneous 9 pneumothorax from occurring in the future. 10 And that would be a massive dose of talc to a 11 tissue that is known to respond with 12 mesotheliomas and tumors when it's -- when 13 it's treated with asbestos. 14 Q. I'm sorry to hear that. 15 The pleural space, you're using 16 medical terms -- 17 A. But back then, you know, they 18 did it as open thoracotomy, so he had an open 19 chest. And -- 20 Q. Use the talc slurring? 21 A. Yes. 22 Q. Okay. 23 A. 5 grams of it. Sterile talc. 24 Q. What do you mean "sterile 25 talc"?</p>
Page 167	Page 169
<p>1 would not be expected to be carcinogenic to 2 the ovary." 3 Do you see that? 4 A. Yes. 5 Q. And then if you go down five 6 bullet points, it says, "No evidence of 7 increased mesotheliomas from pleurodesis for 8 spontaneous pneumothorax." 9 Do you see that there? 10 A. Yes. Yes. 11 Q. Is that what we were talking 12 about from the first page? 13 A. Yes. 14 Q. That's a sclerosing agent, 15 right? 16 A. Yeah. That came about from the 17 experience my son had with a collapsed lung. 18 MR. BOWDEN: I'm going to move 19 to strike, sir. 20 THE WITNESS: And this -- 21 this -- well -- 22 QUESTIONS BY MR. BOWDEN: 23 Q. Go ahead. 24 A. I think it's somewhat important 25 to --</p>	<p>1 A. The talc used for pleurodesis 2 is considered sterile talc because it's going 3 to be used for medical purposes. 4 Q. So that would be pharmaceutical 5 grade? 6 A. Yeah. 7 Q. That'd be 99 percent talc or 8 better? 9 A. Yeah. 10 MR. HEGARTY: Objection to 11 form. 12 QUESTIONS BY MR. BOWDEN: 13 Q. By definition. 14 A. Yeah. And those same talcs 15 have been -- animals have been treated with 16 them and they have not responded with tumors. 17 And we know that that pleural 18 tissue is prime to respond with tumors in 19 humans and rats to a point where the Stanton 20 study, a hallmark study, found that these 21 very same talcs, these cosmetic -- these 22 talcs used pleurodesis did not cause tumors 23 in rats. 24 Very important in my -- the 25 opinion I came to regarding talc and ovarian</p>

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Robert Glenn

<p style="text-align: right;">Page 170</p> <p>1 cancer.</p> <p>2 I can't imagine if ovarian</p> <p>3 tissue were hit with a load like that -- if</p> <p>4 lung tissue is and it doesn't respond, I</p> <p>5 don't think epithelial tissue in the -- in</p> <p>6 the ovary will respond.</p> <p>7 So, sorry to get off on that.</p> <p>8 Q. No, and I -- I'm sorry to hear</p> <p>9 that.</p> <p>10 A. Yeah. Well, he never had</p> <p>11 another spontaneous pneumothorax either from</p> <p>12 his treatment.</p> <p>13 Q. Oh, good.</p> <p>14 A. And he never developed</p> <p>15 mesothelioma.</p> <p>16 Q. Okay. So you had used quite a</p> <p>17 few medical terms. I just want to make sure</p> <p>18 that I understand them.</p> <p>19 A. All right.</p> <p>20 Q. So the spontaneous</p> <p>21 pneumothorax, that's a collapsed lung, right?</p> <p>22 A. That's a collapsed lung, yes.</p> <p>23 Q. And the pleura, that's the</p> <p>24 actual tissue surrounding the outside of the</p> <p>25 lung?</p>	<p style="text-align: right;">Page 172</p> <p>1 Q. Okay. What we just saw as the</p> <p>2 bullet point we just referenced on the other</p> <p>3 page, this is the actual section that</p> <p>4 supports that hypothesis, right?</p> <p>5 A. That's correct.</p> <p>6 Q. And you quote here a study by</p> <p>7 Lange and Mortensen and Groth, "Lung function</p> <p>8 22 to 35 years after treatment of idiopathic</p> <p>9 spontaneous pneumothorax."</p> <p>10 That's like what you just</p> <p>11 described, correct?</p> <p>12 A. Correct.</p> <p>13 Q. "With talc poudrage" -- I don't</p> <p>14 know how to say that.</p> <p>15 A. Poudrage.</p> <p>16 Q. Poudrage.</p> <p>17 -- "or simple drainage thorax,"</p> <p>18 right?</p> <p>19 A. Uhm.</p> <p>20 Q. I'm not asking you to describe</p> <p>21 it, but --</p> <p>22 A. Yes.</p> <p>23 Q. -- that's what you quoted in</p> <p>24 here, correct?</p> <p>25 A. I was just saying in low</p>
<p style="text-align: right;">Page 171</p> <p>1 A. There're two pleural surfaces.</p> <p>2 Q. Okay. Go ahead.</p> <p>3 A. The visceral pleura and the</p> <p>4 parietal pleura.</p> <p>5 Q. Right.</p> <p>6 A. The visceral surrounds the</p> <p>7 lung --</p> <p>8 Q. Is above the diaphragm.</p> <p>9 A. -- and the abdomen -- abdominal</p> <p>10 organs, and the parietal is on the chest</p> <p>11 wall.</p> <p>12 Q. Okay. Okay.</p> <p>13 MR. BOWDEN: I want to go back</p> <p>14 to page 4, Corey. It's just on the</p> <p>15 other side.</p> <p>16 THE WITNESS: I'm sorry. Got</p> <p>17 too many pages. Okay.</p> <p>18 With the table? Oh.</p> <p>19 QUESTIONS BY MR. BOWDEN:</p> <p>20 Q. It's 35.4. It's actually</p> <p>21 page 2 of the document.</p> <p>22 A. Yeah, I have it now.</p> <p>23 Q. Are you okay to keep going,</p> <p>24 sir?</p> <p>25 A. Sure.</p>	<p style="text-align: right;">Page 173</p> <p>1 country, South Carolina, they probably</p> <p>2 wouldn't say poudrage, but --</p> <p>3 Q. Well, then I said it right.</p> <p>4 A. Yeah, right.</p> <p>5 Q. All right. "So the long-term</p> <p>6 effects of lung function of treatment of</p> <p>7 idiopathic spontaneous pneumothorax by talc</p> <p>8 poudrage or simple chest drainage was</p> <p>9 assessed in 114 consecutive patients treated</p> <p>10 at two chest sites in Copenhagen for</p> <p>11 idiopathic spontaneous pneumothorax" --</p> <p>12 Lung collapses, right?</p> <p>13 A. Uh-huh.</p> <p>14 Q. -- "without known origin."</p> <p>15 Right?</p> <p>16 A. Yeah.</p> <p>17 Q. Okay. And you go on there to</p> <p>18 discuss at the very end of it: "None of the</p> <p>19 subjects had developed a mesothelioma."</p> <p>20 A. Yes.</p> <p>21 Q. Right?</p> <p>22 And mesothelioma is a cancer,</p> <p>23 right?</p> <p>24 A. It's a very serious cancer.</p> <p>25 Q. It's an incurable cancer?</p>

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Robert Glenn

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<p>1 A. It is incurable, yes.</p> <p>2 Q. Always a lethal cancer, right?</p> <p>3 A. To my knowledge, yes.</p> <p>4 Q. Okay.</p> <p>5 A. It might be some peritoneals</p> <p>6 survive, but certainly the pleural do not.</p> <p>7 Q. Okay. And I do have to ask</p> <p>8 you: You are not an oncologist, correct?</p> <p>9 A. No, I'm not.</p> <p>10 Q. Okay. And you're not an</p> <p>11 oncologist dealing with ovarian tumors,</p> <p>12 correct?</p> <p>13 A. No.</p> <p>14 Q. In writing this strategy, did</p> <p>15 you consult with a gynecological oncologist?</p> <p>16 A. I did not. I did consult with</p> <p>17 a pulmonary specialist that had considerable</p> <p>18 experience with pleurodesis. I don't know</p> <p>19 whether that was before this time or after,</p> <p>20 but Dr. Veena Antony at the University of</p> <p>21 Florida.</p> <p>22 Q. Okay.</p> <p>23 A. And she essentially was in</p> <p>24 agreement with the hypothesis based upon her</p> <p>25 experience with pleurodesis for malignant</p>	<p>1 Q. Epithelial ovarian cells?</p> <p>2 A. -- and epithelial ovarian</p> <p>3 cells, genetic microarrays.</p> <p>4 Q. Right.</p> <p>5 A. Right.</p> <p>6 Q. And we're going to actually</p> <p>7 talk about that later on.</p> <p>8 A. Okay. Good.</p> <p>9 Q. That's the -- you're referring</p> <p>10 to Mossman and --</p> <p>11 A. Dr. Mossman, yes.</p> <p>12 Q. Yeah. Okay.</p> <p>13 We're going to get to that.</p> <p>14 A. Okay.</p> <p>15 Q. I promise we'll come back to</p> <p>16 it.</p> <p>17 So one of the comments you just</p> <p>18 made in that last paper we were talking about</p> <p>19 was pharmaceutical grade talc. I think you</p> <p>20 said medical grade talc.</p> <p>21 A. The Lange study, yes.</p> <p>22 Q. Okay. So I think it's</p> <p>23 important to understand that there are</p> <p>24 different types of talc, right?</p> <p>25 A. Yeah, the -- these talcs that</p>
Page 175	Page 177
<p>1 pleural mesotheliomas and other causes.</p> <p>2 Q. Okay. And pleural cells are</p> <p>3 different than ovarian cells, correct?</p> <p>4 A. Yeah, they are. Ovarian cells</p> <p>5 or epithelium cells, pleuras from the</p> <p>6 mesoderm.</p> <p>7 Q. Right.</p> <p>8 Mesoderm being the membrane</p> <p>9 lining.</p> <p>10 A. That's correct.</p> <p>11 Q. And in this case what you're</p> <p>12 talking about is the pleural space, right?</p> <p>13 A. That's for the embryologic</p> <p>14 origin of it, yes.</p> <p>15 Q. Okay. Okay. All right. We're</p> <p>16 going to come back --</p> <p>17 A. However, there are epithelial</p> <p>18 cell linings in the lung.</p> <p>19 Q. Right. But I'm talking about</p> <p>20 ovarian cells. Epithelial ovarian cells are</p> <p>21 different?</p> <p>22 A. Yeah, but those epithelial</p> <p>23 cells in the lung would be very similar.</p> <p>24 And some experiments have been</p> <p>25 done using human mesothelial cells and --</p>	<p>1 they use for pleurodesis, they come from the</p> <p>2 same deposits that body powder talcs come</p> <p>3 from.</p> <p>4 Q. Right.</p> <p>5 But they have different</p> <p>6 compositions?</p> <p>7 A. Not necessarily. Not to my</p> <p>8 knowledge.</p> <p>9 Q. Pharmaceutical grade talc is</p> <p>10 defined as having 99 percent talcum in it,</p> <p>11 right?</p> <p>12 MR. BILLINGS-KANG: Object to</p> <p>13 form.</p> <p>14 THE WITNESS: I would have to</p> <p>15 go back and read this FDA</p> <p>16 specification. I cannot recall right</p> <p>17 now, having it been 10, 14 years ago</p> <p>18 when I read that, but I would say it</p> <p>19 is 99 percent talc, yes.</p> <p>20 (Glenn Exhibit 16 marked for</p> <p>21 identification.)</p> <p>22 QUESTIONS BY MR. BOWDEN:</p> <p>23 Q. Okay. I want to hand you what</p> <p>24 I'm going to mark as Exhibit 16.</p> <p>25 A. Okay.</p>

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Robert Glenn

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<p>1 Q. I marked my copy. Bear with me 2 one moment. 3 The last document we were 4 looking at was dated May 3, 2005. This 5 document is dated May 9, 2005. 6 Do you see that? 7 A. Yeah. 8 Q. And this is a follow-up from 9 the NTP talc telephone conference that you 10 had with Luzenac, Meta-Analysis Research 11 Group and Johnson &amp; Johnson, right? 12 A. It appears to be, yes. 13 Q. And this is Steven Mann writing 14 internally at Johnson &amp; Johnson that "we 15 discussed another issue related to the 16 historical use of talc and the treatment of 17 spontaneous lung collapse and how the lack of 18 tumors might help our case," right? 19 A. Yes. 20 Q. And that was a suggestion that 21 you raised, right? 22 A. Yes, it is. 23 Q. Okay. Prior to this suggestion 24 in that phone call of May of 2005, there 25 wasn't a section in their potential report on</p>	<p>1 aware of this hypothesis of this pleurodesis 2 issue. It's certain IARC wasn't aware of it 3 because when it was brought to their 4 attention, someone had to explain what 5 pleurodesis was. 6 Q. Oh, okay. 7 Now, ultimately -- and this is 8 May of 2005 -- 9 A. Yes. 10 Q. -- right? 11 And some of this discussion 12 beyond the diaphragm study is regarding the 13 process for creating a report for submission 14 to the NTP, the 12 ROC. 15 That's what we've been 16 discussed, right? 17 A. Yes. 18 Q. And ultimately what happened 19 was later that year, the NTP withdrew their 20 nomination of talc, right? 21 A. They drew -- withdrew the 10th. 22 Q. Withdrew the nomination of the 23 talc from the 12th Report on Carcinogens. 24 A. Oh, the 12th. I didn't catch 25 that in reviewing my documents, but you may</p>
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<p>1 that issue, right? That was something that 2 you brought and added to the conversation? 3 MR. HEGARTY: Objection. Form. 4 THE WITNESS: I'm sorry, could 5 you repeat that one? 6 QUESTIONS BY MR. BOWDEN: 7 Q. Prior to this telephone 8 conference in May of 2005 -- 9 A. Telephone conference, yeah, 10 right. 11 Q. Yes, sir. 12 -- that was a strategy that you 13 developed to include -- 14 A. I introduced, yes. 15 Q. Okay. Before then, it was not 16 something that was in the review paper that 17 they were writing, correct? 18 MR. HEGARTY: Objection. Form. 19 MR. DONATH: Objection. 20 THE WITNESS: No, not to my 21 knowledge. 22 QUESTIONS BY MR. BOWDEN: 23 Q. Okay. 24 A. I wasn't -- I don't know 25 whether Dr. Huncharek and Dr. Muscat were</p>	<p>1 be correct. 2 Q. Well, you know ultimately that 3 the NTP paper that you had had Meta-Analysis 4 Research Group begin drafting was never 5 submitted to the NTP? 6 A. I do, yes. 7 Q. Because the NTP, that issue 8 just went by the wayside. They withdrew it. 9 A. Yeah, I -- you're recalling 10 some things that now are coming back to me, 11 but I wasn't really aware -- 12 Q. And I understand. 13 A. -- the 12th had been withdrawn. 14 Q. Sure. Right. I just want 15 to -- 16 A. Yeah. 17 Q. -- to show the timeline -- 18 A. Sure. 19 Q. -- for the jury of what's 20 happening here. 21 A. Sure. 22 Q. Before the NTP withdrew their 23 nomination of talc, IARC picked up the issue, 24 right? 25 A. Yes, and I think there was some</p>

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<p>1 communication between NTP and IARC on that.</p> <p>2 Q. Right.</p> <p>3 And so while NTP was</p> <p>4 withdrawing the nomination, there was</p> <p>5 knowledge at that point in time that IARC was</p> <p>6 going to take the issue up and have a working</p> <p>7 group on it, right?</p> <p>8 MR. DONATH: Objection to form.</p> <p>9 THE WITNESS: Yes, now that you</p> <p>10 mention that, that would probably be</p> <p>11 the -- the order that would take</p> <p>12 place. It seems like in this case</p> <p>13 they did have the 10th.</p> <p>14 But IARC generally reviews</p> <p>15 these substances, and then the NTP,</p> <p>16 they essentially endorse them, they</p> <p>17 rubber-stamp.</p> <p>18 QUESTIONS BY MR. BOWDEN:</p> <p>19 Q. Okay. So if anyone were to</p> <p>20 walk into court in this case and say that the</p> <p>21 NTP withdrew their nomination of talc from</p> <p>22 the 12th Report on Carcinogens because they</p> <p>23 concluded that talc was not a carcinogen,</p> <p>24 that would not be accurate?</p> <p>25 MR. DONATH: Objection to form.</p>	<p>1 shift, yeah, yeah.</p> <p>2 QUESTIONS BY MR. BOWDEN:</p> <p>3 Q. Sure.</p> <p>4 And so what happened was that</p> <p>5 the -- the review, the report that was</p> <p>6 created or was in the draft stages --</p> <p>7 A. Uh-huh.</p> <p>8 Q. -- that was shelved for the</p> <p>9 time being, right?</p> <p>10 MR. HEGARTY: Objection. Form.</p> <p>11 THE WITNESS: I'm not -- I</p> <p>12 don't recall it being shelved. It may</p> <p>13 have been.</p> <p>14 QUESTIONS BY MR. BOWDEN:</p> <p>15 Q. Well, I guess --</p> <p>16 A. As you say, we were developing</p> <p>17 those reports for NTP.</p> <p>18 Q. So the contract said?</p> <p>19 A. Yeah.</p> <p>20 Q. Right.</p> <p>21 A. They were for NTP submission.</p> <p>22 Q. Right. So the idea of</p> <p>23 submitting it to the NTP, that idea had been</p> <p>24 shelved, but the idea of continuing on with</p> <p>25 the report and reaching conclusions, that</p>
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<p>1 THE WITNESS: That wouldn't --</p> <p>2 to my knowledge, no, that would not be</p> <p>3 accurate. I don't think that was the</p> <p>4 cause.</p> <p>5 There was some discussion</p> <p>6 between Dr. Jameson and an individual</p> <p>7 with the IARC that you're getting into</p> <p>8 a ball of wax by reviewing talc.</p> <p>9 QUESTIONS BY MR. BOWDEN:</p> <p>10 Q. Okay.</p> <p>11 A. Or words to that effect.</p> <p>12 Q. Well -- and we're switching</p> <p>13 gears, but there's a lot of overlap as you've</p> <p>14 described.</p> <p>15 NTP was withdrawing from the</p> <p>16 issue at the same time they know that IARC is</p> <p>17 picking it up, and that had implications to</p> <p>18 Crowell &amp; Moring and their interactions with</p> <p>19 Meta-Analysis Research Group, right?</p> <p>20 MR. DONATH: Objection to form.</p> <p>21 MR. HEGARTY: Objection to</p> <p>22 form.</p> <p>23 MR. BOWDEN: And I can be more</p> <p>24 specific.</p> <p>25 THE WITNESS: There was a</p>	<p>1 work continued?</p> <p>2 MR. DONATH: Objection to form.</p> <p>3 MR. HEGARTY: Objection to</p> <p>4 form.</p> <p>5 THE WITNESS: Yes. I think I</p> <p>6 did, yes.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. So there were some objections</p> <p>9 and I think your answer overlapped it, so I'm</p> <p>10 going to reask the question to you again.</p> <p>11 The intent to submit that</p> <p>12 report to the NTP, that intent went away when</p> <p>13 the NTP withdrew its nomination?</p> <p>14 A. Yes.</p> <p>15 Q. However, the intent for</p> <p>16 Crowell &amp; Moring to continue with the report</p> <p>17 itself, that continued on --</p> <p>18 MR. HEGARTY: Objection.</p> <p>19 QUESTIONS BY MR. BOWDEN:</p> <p>20 Q. -- exclusive of the NTP</p> <p>21 process?</p> <p>22 MR. DONATH: Objection. Form.</p> <p>23 MR. HEGARTY: Objection. Form.</p> <p>24 THE WITNESS: Yes, I think our</p> <p>25 client was still interested in the</p>

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<p style="text-align: right;">Page 186</p> <p>1 reviews and -- to find out if what was</p> <p>2 the relationship, if any, between</p> <p>3 perineal dusting and ovarian cancer.</p> <p>4 So that continued.</p> <p>5 QUESTIONS BY MR. BOWDEN:</p> <p>6 Q. And at the same time, the</p> <p>7 diaphragm study was still being developed,</p> <p>8 right?</p> <p>9 A. Yes.</p> <p>10 Q. There wasn't as much input on</p> <p>11 the diaphragm study, was there?</p> <p>12 MR. HEGARTY: Objection to</p> <p>13 form.</p> <p>14 MR. DONATH: Objection. Form.</p> <p>15 THE WITNESS: That was proposed</p> <p>16 by Dr. Huncharek, and it was</p> <p>17 meta-analysis, and we didn't -- I</p> <p>18 didn't have a lot of input on that.</p> <p>19 QUESTIONS BY MR. BOWDEN:</p> <p>20 Q. But the NTP proposal was</p> <p>21 proposed by Crowell &amp; Moring?</p> <p>22 A. They --</p> <p>23 Q. On behalf of Luzenac?</p> <p>24 A. Yeah. Yeah.</p> <p>25 Q. Okay.</p>	<p style="text-align: right;">Page 188</p> <p>1 document. It's 100 and, what, 61 pages by my</p> <p>2 count.</p> <p>3 Is that about right to you?</p> <p>4 It's numbered at the bottom.</p> <p>5 A. Yeah, right, with the -- the</p> <p>6 actual text, it's maybe 47, 48 pages.</p> <p>7 Q. Right.</p> <p>8 A. Approximately.</p> <p>9 Q. Right.</p> <p>10 So -- and you can see on the</p> <p>11 first page here, this is an e-mail from you</p> <p>12 dated July 27, 2005, to Luzenac, Johnson &amp;</p> <p>13 Johnson, copying Ridgway Hall, right?</p> <p>14 A. Yes.</p> <p>15 Q. And it says, "Subject,</p> <p>16 deliverables from Huncharek and Muscat,"</p> <p>17 right?</p> <p>18 A. Yes.</p> <p>19 Q. And we go down to the body of</p> <p>20 this on the first page, it says, "We recently</p> <p>21 received documents from Dr. Huncharek and</p> <p>22 Muscat in response to our agreement providing</p> <p>23 for comments to the NTP and for conducting a</p> <p>24 meta-analysis."</p> <p>25 And then you list out a total</p>
<p style="text-align: right;">Page 187</p> <p>1 THE WITNESS: I hate to do this</p> <p>2 to you, but let's do one more. I'm</p> <p>3 sorry.</p> <p>4 MR. BOWDEN: It's completely</p> <p>5 okay. I'm going to sit tight. We can</p> <p>6 take a shorter break that way.</p> <p>7 THE WITNESS: If y'all can just</p> <p>8 sit by, I'll be right back.</p> <p>9 VIDEOGRAPHER: The time is now</p> <p>10 11:37. Going off the record.</p> <p>11 (Off the record at 11:37 a.m.)</p> <p>12 VIDEOGRAPHER: Okay. The time</p> <p>13 is now 11:40. Back on the record.</p> <p>14 (Glenn Exhibit 17 marked for</p> <p>15 identification.)</p> <p>16 QUESTIONS BY MR. BOWDEN:</p> <p>17 Q. All right. I'm going to hand</p> <p>18 you what's marked as Exhibit 17, sir.</p> <p>19 A. All right. Okay.</p> <p>20 Q. Do you recognize this document</p> <p>21 in your review for this deposition?</p> <p>22 A. Yes, I do.</p> <p>23 Q. Did you spend some time on it?</p> <p>24 A. I looked through it, yes.</p> <p>25 Q. And this is a pretty good-sized</p>	<p style="text-align: right;">Page 189</p> <p>1 of eight -- there's five on the first page --</p> <p>2 the following documents: Executive summary,</p> <p>3 talc and ovarian cancer, a critical review.</p> <p>4 Now, that number 2 there, talc</p> <p>5 and ovarian cancer, a critical review, that</p> <p>6 would be the report for the NTP --</p> <p>7 A. Yes.</p> <p>8 Q. -- that's ultimately scratched,</p> <p>9 right?</p> <p>10 A. That would be the report, yes.</p> <p>11 Q. I said "scratched."</p> <p>12 "Ultimately not submitted" is the right way</p> <p>13 of saying that, right?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. And you see on the end</p> <p>16 of number 2 it says, "clean copy," right?</p> <p>17 A. Yes.</p> <p>18 Q. And then 3 it says, "red line</p> <p>19 version," right?</p> <p>20 A. Yeah. Correct.</p> <p>21 Q. Then you've got some SEER</p> <p>22 information, and then 5 is the draft</p> <p>23 manuscript of use of cosmetic talc on</p> <p>24 contraceptive diaphragms and risk of ovarian</p> <p>25 cancer.</p>

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<p>1 A. Right.</p> <p>2 Q. That's the meta-analysis -- the</p> <p>3 diaphragm meta-analysis, right?</p> <p>4 A. Right.</p> <p>5 Q. If you'll turn with me to the</p> <p>6 second page, I got a couple of tables and two</p> <p>7 figures that are listed out as 6, 7 and 8,</p> <p>8 right?</p> <p>9 A. Correct.</p> <p>10 Q. And those were submitted to --</p> <p>11 those are drafts of forest plots and a couple</p> <p>12 of tables that were summarizing data within</p> <p>13 the article itself?</p> <p>14 A. Right.</p> <p>15 Q. And those were given to you,</p> <p>16 Johnson &amp; Johnson and Luzenac, as well as</p> <p>17 Crowell &amp; Moring, to provide your edits and</p> <p>18 comments on, true?</p> <p>19 MR. HEGARTY: Objection to</p> <p>20 form.</p> <p>21 MR. DONATH: Objection to form.</p> <p>22 THE WITNESS: Yeah, we were</p> <p>23 asked to review this.</p> <p>24 QUESTIONS BY MR. BOWDEN:</p> <p>25 Q. Okay.</p>	<p>1 pleurodesis. It outlined 11 different</p> <p>2 hypotheses, I think, of talc and ovarian</p> <p>3 cancers and why there might not be a</p> <p>4 correlation.</p> <p>5 A. Yeah, okay.</p> <p>6 Q. Is that correct?</p> <p>7 A. I think that -- I think you're</p> <p>8 right about that, yes.</p> <p>9 Q. Okay. And then it says, if we</p> <p>10 continue on here, "You will see we question</p> <p>11 inclusion of sections 3 and 4 and are</p> <p>12 undecided whether they belong in scientific</p> <p>13 comments to the NTP or add any value to the</p> <p>14 thrust of the comments. Your opinions on</p> <p>15 whether to recommend deleting these sections</p> <p>16 or placing them in the appendix will be</p> <p>17 welcomed. You will note that we recommended</p> <p>18 the section related to talc mineralogy and</p> <p>19 its similarity/dissimilarity to asbestos</p> <p>20 needs attention by Rich Zazenski or a</p> <p>21 mineralogist."</p> <p>22 A. Yes.</p> <p>23 Q. Did you ever consult with a</p> <p>24 mineralogist in preparing that report?</p> <p>25 A. I did not.</p>
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<p>1 A. Or we did review it, yes.</p> <p>2 Q. Right.</p> <p>3 The meta-analysis document,</p> <p>4 Item Number 5: "Seems well written, and</p> <p>5 conclusions are supported by the data."</p> <p>6 A. Yeah.</p> <p>7 Q. "However, the critical</p> <p>8 review" -- again, that's the NTP report,</p> <p>9 right?</p> <p>10 A. Uh-huh.</p> <p>11 Q. -- "Items 2 and 3 is not as</p> <p>12 well done and will require some revisions by</p> <p>13 the authors after receiving our collective</p> <p>14 comments."</p> <p>15 And now this sequence, this is</p> <p>16 after -- after the strategy document you sent</p> <p>17 around, right?</p> <p>18 MR. HEGARTY: Objection. Form.</p> <p>19 THE WITNESS: The strategy</p> <p>20 document on pleurodesis?</p> <p>21 QUESTIONS BY MR. BOWDEN:</p> <p>22 Q. Yes, sir.</p> <p>23 A. Yeah.</p> <p>24 Q. Well, it's actually -- it was a</p> <p>25 strategy document that was more than just</p>	<p>1 MR. DONATH: Objection to form.</p> <p>2 QUESTIONS BY MR. BOWDEN:</p> <p>3 Q. Do you know whether the authors</p> <p>4 ever consulted with one?</p> <p>5 A. I think they may have.</p> <p>6 Q. But you don't recall?</p> <p>7 A. I don't know who it was. But</p> <p>8 Dr. Muscat, who's principal on this, he's not</p> <p>9 a mineralogist and had poor understanding of</p> <p>10 mineralogy, and we felt that it, you know, it</p> <p>11 shouldn't go out without those corrections</p> <p>12 being made.</p> <p>13 Q. I see. Okay.</p> <p>14 "We are in hopes of getting our</p> <p>15 collective comments back to Huncharek and</p> <p>16 Muscat by August 12 and would appreciate your</p> <p>17 comments by August 9th," right?</p> <p>18 So you were establishing a</p> <p>19 timeline to get these comments in --</p> <p>20 A. Yes.</p> <p>21 Q. -- correct?</p> <p>22 So now let's turn to some of</p> <p>23 the actual pages in this -- this report.</p> <p>24 A. Yeah.</p> <p>25 Q. If you'll turn to -- I'm going</p>

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<p>1 to use, because it's easier to see, is P138.5</p> <p>2 at the bottom. It's in bold.</p> <p>3 A. Okay.</p> <p>4 Q. And this is going to be</p> <p>5 called -- strike that.</p> <p>6 This is the cover page --</p> <p>7 A. Oh, I've got 4.</p> <p>8 Q. -- to the draft report.</p> <p>9 A. Wait a minute. I've got 5.</p> <p>10 Yeah, this is the cover.</p> <p>11 Q. Oh, I'm sorry. You with me</p> <p>12 now?</p> <p>13 A. Yeah.</p> <p>14 Q. Okay. Great.</p> <p>15 A. This is the cover page.</p> <p>16 Q. Right. Right.</p> <p>17 "Talc and Ovarian Cancer: A</p> <p>18 Critical Review."</p> <p>19 You see where that's written?</p> <p>20 A. Yes.</p> <p>21 Q. "A report provided to Crowell &amp;</p> <p>22 Moring by Michael Huncharek and Josh Muscat."</p> <p>23 Do you see that there?</p> <p>24 A. Yes.</p> <p>25 Q. All right. And if you turn to</p>	<p>1 well --</p> <p>2 A. Yes. Yes.</p> <p>3 Q. -- right?</p> <p>4 So what I want to draw your</p> <p>5 attention to is page .35, if you can go to</p> <p>6 page .35 for me.</p> <p>7 A. Okay. Okay.</p> <p>8 Q. Now, you see Section 8 there?</p> <p>9 A. Yeah.</p> <p>10 Q. Which is talc pleurodesis?</p> <p>11 A. Right.</p> <p>12 Q. That entire section was added</p> <p>13 as a result of your strategy paper, right?</p> <p>14 A. It appears to be, yes.</p> <p>15 Q. And it continues on to</p> <p>16 page .36, page .37, right?</p> <p>17 A. Yes.</p> <p>18 Q. So it appears to be just over</p> <p>19 two pages worth of information, right?</p> <p>20 A. Yes.</p> <p>21 Q. And but for your involvement --</p> <p>22 strike that.</p> <p>23 Without you recommending this</p> <p>24 to be in there, this would not have been in</p> <p>25 there, true?</p>
Page 195	Page 197
<p>1 page 22, .22.</p> <p>2 A. Okay.</p> <p>3 Q. You with me?</p> <p>4 A. Yeah.</p> <p>5 Q. The bolded section is called 5,</p> <p>6 testing the talc hypothesis, right?</p> <p>7 A. Right.</p> <p>8 Q. And this is the introductory</p> <p>9 section, right, of what -- of what hypotheses</p> <p>10 are going to be discussed within this</p> <p>11 article, right?</p> <p>12 A. Yes, this is his initial</p> <p>13 introduction, yes.</p> <p>14 Q. And you can see on page 19 that</p> <p>15 it starts listing them out, and it's 1</p> <p>16 through 8 --</p> <p>17 A. Page?</p> <p>18 Q. I'm sorry, page 23.</p> <p>19 A. Okay. Yes.</p> <p>20 Q. And number 8 is the talc</p> <p>21 pleurodesis section, right, or the</p> <p>22 introductory language?</p> <p>23 A. Yes.</p> <p>24 Q. And then on page 24, the next</p> <p>25 page, you've got 9 through 11 listed as</p>	<p>1 MR. HEGARTY: Objection. Form.</p> <p>2 MR. DONATH: Objection. Form.</p> <p>3 THE WITNESS: I brought this to</p> <p>4 the attention of the authors. They</p> <p>5 decided to include it.</p> <p>6 QUESTIONS BY MR. BOWDEN:</p> <p>7 Q. I see.</p> <p>8 Was this paper ultimately</p> <p>9 published?</p> <p>10 MR. HEGARTY: Objection. Form.</p> <p>11 THE WITNESS: Yes. Yes, it</p> <p>12 was. I think.</p> <p>13 QUESTIONS BY MR. BOWDEN:</p> <p>14 Q. It was published, right?</p> <p>15 A. Yeah.</p> <p>16 Q. And it took a while to get</p> <p>17 published, didn't it?</p> <p>18 MR. BILLINGS-KANG: Objection.</p> <p>19 Form.</p> <p>20 THE WITNESS: It may have, yes.</p> <p>21 QUESTIONS BY MR. BOWDEN:</p> <p>22 Q. And the reason it took a while</p> <p>23 to get published is that it had been rejected</p> <p>24 by four separate journals prior to being</p> <p>25 accepted, right?</p>

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<p style="text-align: right;">Page 198</p> <p>1 MR. HEGARTY: Objection. Form. 2 MR. DONATH: Objection. Form. 3 MR. BILLINGS-KANG: Objection. 4 Form. 5 THE WITNESS: It may have been, 6 yes. 7 QUESTIONS BY MR. BOWDEN: 8 Q. Well, I don't know about may 9 have been. It actually was rejected -- 10 A. Okay. 11 Q. -- by numerous articles, 12 right -- or journals? 13 A. By some journals, yes. 14 Q. Okay. Do you know that we took 15 the deposition of Dr. Muscat in this 16 litigation? 17 A. I was aware of that, yes. 18 Q. Did you review his testimony? 19 A. No, I did not. 20 Q. Were you provided with any sort 21 of summary of what his testimony is? 22 A. No, I was not. 23 Q. Okay. Would it surprise you to 24 learn that Dr. Muscat says that this paper 25 was never published?</p>	<p style="text-align: right;">Page 200</p> <p>1 QUESTIONS BY MR. BOWDEN: 2 Q. I hand you what I'm labeling as 3 Exhibit Number 18. There you go, sir. 4 A. Okay. 5 Q. Did you review this article in 6 preparing for your deposition? 7 A. I looked -- yes, I saw it in 8 the documents that were provided. 9 Q. And this is the document that 10 you recall -- this publication was originally 11 the NTP report, right -- 12 A. That's -- 13 Q. -- that you commissioned? 14 A. That was the basis of this 15 paper, yes. 16 Q. Okay. And you can see at the 17 top, the title changes just slightly to 18 "Perineal talc use and ovarian cancer: A 19 critical review"? 20 MR. HEGARTY: Objection. Form. 21 THE WITNESS: Yes. 22 QUESTIONS BY MR. BOWDEN: 23 Q. And that's not uncommon to have 24 minor edits, right, like that? 25 MR. HEGARTY: Objection. Form.</p>
<p style="text-align: right;">Page 199</p> <p>1 MR. HEGARTY: Objection. Form. 2 THE WITNESS: I think it was 3 published. 4 QUESTIONS BY MR. BOWDEN: 5 Q. You think he's wrong? 6 MR. HEGARTY: Objection. Form. 7 THE WITNESS: I think it was 8 published in a European journal. 9 QUESTIONS BY MR. BOWDEN: 10 Q. Journal of Cancer Prevention? 11 A. Yeah. Yeah. Right. 12 Q. Ultimately what started off as 13 a proposal from Crowell &amp; Moring to conduct a 14 summary review for the NTP winds up being 15 published in the European Journal of Cancer 16 Prevention, right? 17 MR. HEGARTY: Objection. Form. 18 THE WITNESS: Yeah, it was 19 mentioned in their agreement that they 20 put forward their proposal that they 21 would submit articles for publication, 22 so I don't know that's so surprising. 23 (Glenn Exhibit 18 marked for 24 identification.) 25</p>	<p style="text-align: right;">Page 201</p> <p>1 THE WITNESS: Well, yeah, 2 oftentimes the subject of the study, 3 the manuscript that's submitted for 4 publication will differ. 5 QUESTIONS BY MR. BOWDEN: 6 Q. Sure. 7 A. Sure. 8 Q. And that's based on reviewer 9 comments? 10 MR. HEGARTY: Objection. Form. 11 THE WITNESS: No, it's based 12 upon the author. The last paper we 13 submitted -- 14 QUESTIONS BY MR. BOWDEN: 15 Q. Okay. Yeah. 16 A. The last paper me and my 17 colleagues submitted, the -- we didn't use 18 the report name on it. We couched it in 19 different terms. 20 Q. Right. 21 And this doesn't indicate, at 22 least on its title, that it was a report 23 prepared for Crowell &amp; Moring, right? 24 A. No, it does not. 25 Q. Okay. And you can see that on</p>

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<p>1 the --</p> <p>2 A. That would -- that wouldn't be</p> <p>3 normal for a journal to publish that upfront.</p> <p>4 Q. That's right.</p> <p>5 It says in the bottom -- or</p> <p>6 excuse me. The received date was October 31,</p> <p>7 2006, accepted February 13th of 2007.</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. Now, let's turn to -- it'll be</p> <p>11 point -- excuse me .7 for you.</p> <p>12 A. Okay. Yes.</p> <p>13 Q. And you see down there where it</p> <p>14 says "acknowledgement"?</p> <p>15 A. Yes.</p> <p>16 Q. And it says, "Supported by a</p> <p>17 contract from Crowell &amp; Moring, Inc., and</p> <p>18 Public Health Service Grant," and then it</p> <p>19 lists the number?</p> <p>20 A. Yeah.</p> <p>21 Q. Okay. And the contract from</p> <p>22 Crowell &amp; Moring, that's the original</p> <p>23 contract we've been discussing today --</p> <p>24 A. That's our agreement.</p> <p>25 Q. -- that Johnson &amp; Johnson paid</p>	<p>1 that in, the acknowledgement.</p> <p>2 Q. They should be acknowledged,</p> <p>3 right?</p> <p>4 MR. HEGARTY: Objection. Form.</p> <p>5 MR. DONATH: Objection to form.</p> <p>6 THE WITNESS: He was being paid</p> <p>7 by Crowell &amp; Moring. I don't know why</p> <p>8 he couched it this way. Dr. Huncharek</p> <p>9 differed in his acknowledgement.</p> <p>10 QUESTIONS BY MR. BOWDEN:</p> <p>11 Q. So there's nowhere in this</p> <p>12 paper that says "supported by funds received</p> <p>13 from Johnson &amp; Johnson," correct?</p> <p>14 A. No, not to my knowledge. No.</p> <p>15 Q. There's nowhere in this paper</p> <p>16 that acknowledges that funds supporting this</p> <p>17 paper were received by Luzenac?</p> <p>18 A. No.</p> <p>19 MR. DONATH: Objection to form.</p> <p>20 QUESTIONS BY MR. BOWDEN:</p> <p>21 Q. The only thing that's listed</p> <p>22 here is Crowell Moring and a Public Health</p> <p>23 Service Grant, correct?</p> <p>24 A. Yes.</p> <p>25 Q. And it says "Crowell &amp; Moring,</p>
Page 203	Page 205
<p>1 half of?</p> <p>2 A. Yes.</p> <p>3 Q. Imerys paid half of?</p> <p>4 A. Yes.</p> <p>5 Q. Or excuse me, Luzenac paid half</p> <p>6 of?</p> <p>7 A. Yes.</p> <p>8 Q. And the funds went through</p> <p>9 Crowell &amp; Moring?</p> <p>10 A. Yes, they -- Luzenac was our</p> <p>11 client, yes.</p> <p>12 Q. Right. It wasn't Crowell &amp;</p> <p>13 Moring's money. It was the client's money,</p> <p>14 right?</p> <p>15 MR. HEGARTY: Objection. Form.</p> <p>16 MR. DONATH: Objection to form.</p> <p>17 THE WITNESS: Yes.</p> <p>18 QUESTIONS BY MR. BOWDEN:</p> <p>19 Q. Okay. And do you see anywhere</p> <p>20 in this paper where Johnson &amp; Johnson or</p> <p>21 Luzenac are credited with funding?</p> <p>22 A. I don't. Doctor --</p> <p>23 Q. In fact, do you see --</p> <p>24 A. Dr. Muscat, I guess he was the</p> <p>25 primary author, and he's the one that put</p>	<p>1 Inc."</p> <p>2 Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. Crowell &amp; Moring, LLP, is who</p> <p>5 you worked for, right?</p> <p>6 A. That's right.</p> <p>7 Q. What is Crowell &amp; Moring, Inc.?</p> <p>8 A. This was evidently a mistake by</p> <p>9 Dr. Muscat.</p> <p>10 Q. It doesn't say Crowell &amp; Moring</p> <p>11 law firm, does it?</p> <p>12 A. No. We didn't ask -- he didn't</p> <p>13 ask us about our title. I'm surprised he</p> <p>14 didn't pick it up from correspondence.</p> <p>15 Q. You saw drafts of this document</p> <p>16 before it was submitted, right?</p> <p>17 MR. HEGARTY: Objection. Form.</p> <p>18 THE WITNESS: I did see -- I</p> <p>19 did see a draft of this.</p> <p>20 QUESTIONS BY MR. BOWDEN:</p> <p>21 Q. Crowell &amp; Moring never asked to</p> <p>22 be identified as a defense law firm, correct?</p> <p>23 MR. BILLINGS-KANG: Object to</p> <p>24 form.</p> <p>25 MR. DONATH: Objection. Form.</p>

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<p>1 THE WITNESS: The journals 2 require the author to disclose this 3 information. We, as the sponsor of 4 it, we didn't have anything to do with 5 it. 6 He chose to put that on there, 7 and you'd best ask him why he chose 8 that way. 9 QUESTIONS BY MR. BOWDEN: 10 Q. When you received the draft 11 manuscript -- all right. 12 You're not cited as an author 13 in here? 14 A. No, I'm not. I was not an 15 author. 16 Q. Johnson &amp; Johnson isn't cited 17 as an author? 18 MR. HEGARTY: Objection. Form. 19 THE WITNESS: They had -- they 20 didn't have significant contribution 21 to it either. 22 QUESTIONS BY MR. BOWDEN: 23 Q. Luzenac didn't get cited as an 24 author either? 25 MR. DONATH: Objection to form.</p>	<p>1 A. Yes. 2 Q. And this is -- this is actually 3 the section that you proposed in your 4 strategy, right? 5 MR. HEGARTY: Objection. Form. 6 THE WITNESS: This is the 7 section that I brought to their 8 attention, the hypothesis of 9 pleurodesis and how that might relate 10 to ovarian cancer. 11 They prepared this. 12 QUESTIONS BY MR. BOWDEN: 13 Q. I see. 14 A. They drafted this, prepared 15 this. This is their language. 16 Q. Let's go on down to the second 17 paragraph underneath there. It should say, 18 "The safety of talc pleurodesis." 19 A. Yes. 20 Q. "The safety of talc pleurodesis 21 has been clinically recognized anecdotally 22 for many decades but also supported by 23 clinical studies," right? 24 A. Yes. 25 Q. "In a group of 70 patients</p>
Page 207	Page 209
<p>1 THE WITNESS: No, they did not 2 have contribution to the paper. 3 QUESTIONS BY MR. BOWDEN: 4 Q. Okay. If you turn to page .6 5 for me. 6 A. Okay. 7 Q. Here it says "therapeutic uses 8 of talc"? 9 A. Yes. 10 Q. It says, "Cosmetic grade talc 11 is used therapeutically to treat nonmalignant 12 and malignant pulmonary disease." 13 A. Yes. 14 Q. Do you see where I'm reading 15 from? 16 A. Yes. 17 Q. "The insufflation causes 18 adhesions between the parietal and visceral 19 pleura and is used in the treatment of 20 bronchopleural fistulas, malignant pleural 21 effusions and pneumothorax," right? 22 A. Yes. 23 Q. A collapse of the lung from 24 changes in the intrapleural pressure in the 25 chest cavity, right?</p>	<p>1 medically treated with talc pleurodesis, none 2 developed subsequent malignancies after 3 follow-up for outcomes." 4 Do you see that? 5 A. Yes. 6 Q. "In 99 patients undergoing 7 fluoroscopy in asbestos-free talc pleurodesis 8 from spontaneous pneumothorax between 1954 9 and 1964, Lange, et al., none developed 10 malignant mesothelioma as of 1985." 11 A. That's correct. 12 MR. BOWDEN: Corey, can we do a 13 split screen? Can you pull up 14 P1.0035.4? 15 Can you pull up that whole 16 section there, the Lange section, 17 please? 18 QUESTIONS BY MR. BOWDEN: 19 Q. You would agree with me that 20 the Lange article is quoted in the ultimately 21 published -- strike that. 22 The Lange study is quoted in 23 this article which was published, correct? 24 MR. DONATH: Objection. Form. 25 THE WITNESS: Yes, it is.</p>



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<p style="text-align: right;">Page 210</p> <p>1 QUESTIONS BY MR. BOWDEN: 2 Q. And the Lange study was exactly 3 what you brought to their attention, correct? 4 A. Yes. 5 MR. DAVANT: Object to form. 6 QUESTIONS BY MR. BOWDEN: 7 Q. And the takeaway that the 8 authors have from the Lange study in their 9 published review, none developed malignant 10 mesothelioma, right? 11 MR. DONATH: Objection. Form. 12 THE WITNESS: Yes. 13 QUESTIONS BY MR. BOWDEN: 14 Q. Last line of your summary of 15 strategies to them is "none of the subjects 16 had developed a mesothelioma." 17 Do you see that there? 18 A. Yes, that's correct. 19 Q. And they've built out this 20 section that you gave them, right? 21 MR. DONATH: Objection. Form. 22 MR. HEGARTY: Objection. Form. 23 THE WITNESS: You mean build 24 out? 25</p>	<p style="text-align: right;">Page 212</p> <p>1 section on mineralogy as well, right? 2 A. Yes, we recommended that also. 3 Q. And that's another thing that 4 was added in there -- 5 MR. HEGARTY: Objection. Form. 6 QUESTIONS BY MR. BOWDEN: 7 Q. -- at your recommendation, 8 true? 9 A. Yes. 10 Q. And, in fact, when you 11 recommended this to them, you didn't just say 12 that they needed to have a mineralogy section 13 added, you said you need to get a consult 14 with a mineralogist. 15 A. I suggested that, yes. 16 Q. Okay. You don't know whether 17 that ever happened? 18 A. No, I don't. 19 Q. You'd agree with me that 20 there's no mineralogist cited in here as a 21 consulting -- 22 A. There is not. 23 Q. -- person? 24 No mineralogist listed as an 25 author?</p>
<p style="text-align: right;">Page 211</p> <p>1 QUESTIONS BY MR. BOWDEN: 2 Q. Meta-Analysis Research Group 3 took what you gave them and devoted almost a 4 column and a half and their article to it, 5 right? 6 MR. DONATH: Objection to form. 7 MR. HEGARTY: Objection. Form. 8 THE WITNESS: Yes, they 9 discussed this subject which I brought 10 to their attention, and they used some 11 of my text. 12 QUESTIONS BY MR. BOWDEN: 13 Q. I'm sorry, I didn't hear the 14 last part. They used some of your text? 15 A. They used some of my text from 16 my hypothesis. 17 Q. I want to go back to -- still 18 using this article, that's going to be -- 19 A. Okay. 20 Q. -- Exhibit 18. 21 MR. BOWDEN: If you go to 22 P2006.2, Corey. 23 THE WITNESS: 6.2. Okay. 24 QUESTIONS BY MR. BOWDEN: 25 Q. You see there's an entire</p>	<p style="text-align: right;">Page 213</p> <p>1 A. There is none, which would 2 imply they reworded it on their own, 3 possibly. 4 Q. You said Dr. Muscat was a poor 5 mineralogist, right? 6 MR. HEGARTY: Objection. Form. 7 THE WITNESS: I said he did not 8 have an understanding. Anyone can 9 read the literature and form the 10 opinions and couch them in text -- or 11 in words. And maybe he did that, I 12 don't know. 13 QUESTIONS BY MR. BOWDEN: 14 Q. You said that Dr. Muscat was a 15 poor mineralogist. 16 A. I didn't say he was a 17 mineralogist at all. I think I said he did 18 not have knowledge of mineralogy and there 19 were problems with his initial work. 20 Q. I see. 21 A. And recommended that a 22 mineralogist be consulted in revising it. 23 Q. There's also a section in here 24 on exposure via diaphragms, right? 25 A. What page is that?</p>

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<p>1 Q. .4. 2 A. Yes. 3 Q. And so the diaphragm study uses 4 some of this same data, right? 5 MR. HEGARTY: Objection. Form. 6 THE WITNESS: It uses the data 7 that Dr. Huncharek did in his 8 research, in his earlier research, 9 yes. 10 QUESTIONS BY MR. BOWDEN: 11 Q. Right. 12 And that was the data that was 13 sponsored and paid for by Johnson &amp; Johnson 14 as well as Imerys -- or Luzenac; is that 15 correct? 16 MR. HEGARTY: Objection. Form. 17 MR. DONATH: Objection to form. 18 THE WITNESS: Yeah, the one 19 paper was, yes. 20 QUESTIONS BY MR. BOWDEN: 21 Q. Okay. Prior to publication, 22 you mentioned that IARC -- the issue was 23 raised in IARC about pleurodesis? 24 A. Yes. 25 Q. And that was raised at your</p>	<p>1 Q. The issue of pleurodesis at 2 IARC. 3 MR. HEGARTY: Objection. Form. 4 THE WITNESS: She -- that was 5 raised at IARC. 6 QUESTIONS BY MR. BOWDEN: 7 Q. I understand. 8 But you didn't reach out to her 9 directly, right? 10 A. No. I informed her that the 11 meeting was taking place. We had discussed 12 the pleurodesis issue. I said this is 13 something that needs to be a part of the IARC 14 review. 15 Q. So -- 16 A. And that's when we found out 17 later, I suppose, that IARC didn't even 18 understand pleurodesis and that talc was used 19 in 5 to 20 grams on lung tissue. 20 Q. Okay. When you had this 21 discussion with Dr. Antony, had IARC already 22 announced that it was going to consider talc? 23 A. Yes. 24 Q. When you had this discussion 25 with Dr. Antony, had IARC already identified</p>
Page 215	Page 217
<p>1 suggestion, right? 2 MR. HEGARTY: Objection. Form. 3 THE WITNESS: It was raised 4 through comments I made, not to IARC 5 but Dr. Antony, who had experience 6 with pleurodesis and who I met with at 7 an American Thoracic Society meeting 8 and we discussed it. 9 After that, it came out that 10 IARC was going to review talc, and I 11 contacted her and said, you know, this 12 is taking place by IARC, and I think 13 you have something to provide. 14 QUESTIONS BY MR. BOWDEN: 15 Q. Dr. Antony, what role did he 16 play in the IARC working group? 17 A. It's not a he. A she. 18 Q. I'm sorry. Dr. Antony, what 19 role did she play at the IARC working group 20 proceedings? 21 A. She was a working group member. 22 Q. Right. 23 And that issue wasn't raised to 24 Dr. Antony directly, was it? 25 A. What issue?</p>	<p>1 the working group participants? 2 A. I don't think so. I'm not 3 sure, but I don't think so. 4 Q. What time did you have this 5 conversation with Dr. Antony? 6 A. I don't recall the exact date. 7 Q. Was it in 2006? 8 A. I don't recall the date. It 9 may have been earlier. I don't -- it would 10 have been after I learned that IARC was going 11 to review talc. And after my conversation 12 with her, I did not have any other 13 conversation with her about the subject. 14 Q. Has she been on prior IARC 15 working groups, to your knowledge? 16 A. I don't think so. 17 That's part of the problem I 18 have with IARC working groups. 19 Q. What do you mean? 20 A. They have their little cadre 21 that they call in for most of them. 22 Q. It's a low turnover rate? 23 A. You see the same names over and 24 over. 25 Q. Right.</p>

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<p style="text-align: right;">Page 218</p> <p>1 A. Yeah.</p> <p>2 Q. And we're going to explore some</p> <p>3 of that.</p> <p>4 A. Good.</p> <p>5 Q. I think now --</p> <p>6 MR. BOWDEN: Go off the record</p> <p>7 just for a second.</p> <p>8 VIDEOGRAPHER: The time is now</p> <p>9 12:06. Going off the record.</p> <p>10 (Off the record at 12:06 p.m.)</p> <p>11 VIDEOGRAPHER: Okay. The time</p> <p>12 is now 12:16. Back on the record.</p> <p>13 QUESTIONS BY MR. BOWDEN:</p> <p>14 Q. So I wanted to ask you a couple</p> <p>15 of questions in follow-up to the article we</p> <p>16 were just looking at. That was Exhibit</p> <p>17 Number 18.</p> <p>18 A. Yes.</p> <p>19 Q. You know, we had seen earlier</p> <p>20 when you were attaching your strategies to be</p> <p>21 taken into consideration by the authors that</p> <p>22 you recommended that they consult with</p> <p>23 Mr. Zazenski or with a mineralogist, right?</p> <p>24 A. Yes. Yes.</p> <p>25 Q. And you don't know that they</p>	<p style="text-align: right;">Page 220</p> <p>1 recently published, you actually gave</p> <p>2 acknowledgements to people who helped you out</p> <p>3 with editing the manuscript.</p> <p>4 A. Acknowledgement, yes.</p> <p>5 Q. You cited them in there --</p> <p>6 A. Acknowledging them.</p> <p>7 Q. -- at the end of -- right.</p> <p>8 A. Yeah.</p> <p>9 Q. And at the end of the paper,</p> <p>10 you also gave acknowledgements to people who</p> <p>11 helped you out with simple things like</p> <p>12 editing the tables, didn't you?</p> <p>13 A. I may have. I don't recall.</p> <p>14 But that was acknowledgement, not listed as</p> <p>15 an author.</p> <p>16 Q. Okay. In this, is there any</p> <p>17 mineralogist listed as acknowledged?</p> <p>18 A. I don't know if they used one.</p> <p>19 Q. You're not acknowledged in this</p> <p>20 paper either, are you?</p> <p>21 A. No. It would have been</p> <p>22 improper for me to be acknowledged in this</p> <p>23 article.</p> <p>24 MR. BOWDEN: Move to strike the</p> <p>25 last answer.</p>
<p style="text-align: right;">Page 219</p> <p>1 didn't consult with a mineralogist, right?</p> <p>2 A. I don't.</p> <p>3 Q. And you don't know that they</p> <p>4 didn't consult with Mr. Zazenski, do you?</p> <p>5 A. I don't.</p> <p>6 Q. Okay. If they did, that</p> <p>7 person's not cited or acknowledged in any way</p> <p>8 in this paper, correct?</p> <p>9 MR. DONATH: Objection. Form.</p> <p>10 THE WITNESS: Well, just that</p> <p>11 they talked to him about it and he</p> <p>12 pointed out some papers they should</p> <p>13 read and such, he shouldn't be cited</p> <p>14 as an author.</p> <p>15 QUESTIONS BY MR. BOWDEN:</p> <p>16 Q. I see.</p> <p>17 A. Journals have gotten very</p> <p>18 strict about that now. We had a recent</p> <p>19 paper, and we had justified some radiologists</p> <p>20 that read the X-rays, so -- and we did it in</p> <p>21 one paper, which was on the medical effect,</p> <p>22 and we didn't do it in the paper on dust</p> <p>23 characterization of exposure because they</p> <p>24 didn't contribute to it.</p> <p>25 Q. But in your 2013 paper that you</p>	<p style="text-align: right;">Page 221</p> <p>1 QUESTIONS BY MR. BOWDEN:</p> <p>2 Q. All right. Let's talk about</p> <p>3 IARC now.</p> <p>4 A. All right.</p> <p>5 Q. So IARC is the International</p> <p>6 Agency for Research on Cancer, right?</p> <p>7 A. That's correct.</p> <p>8 Q. And that's part of the World</p> <p>9 Health Organization?</p> <p>10 A. Of WHO, yes.</p> <p>11 Q. Right.</p> <p>12 And you're familiar with both</p> <p>13 those organizations, right?</p> <p>14 A. Yes.</p> <p>15 Q. And unlike NTP, where people</p> <p>16 can be invited to come and comment directly,</p> <p>17 IARC process requires nomination of</p> <p>18 observers, right?</p> <p>19 A. Yes.</p> <p>20 Q. And observers, that's a</p> <p>21 different process, isn't it?</p> <p>22 A. Yes.</p> <p>23 Q. I'm sorry, I'm moving around.</p> <p>24 That's a different process,</p> <p>25 right?</p>

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<p>1 A. Yes. Yes.</p> <p>2 Q. And you were involved on behalf</p> <p>3 of a number of talc manufacturers in</p> <p>4 coordinating the message from industry at</p> <p>5 IARC, right?</p> <p>6 MR. HEGARTY: Objection. Form.</p> <p>7 THE WITNESS: I wouldn't say we</p> <p>8 coordinated the message. We had input</p> <p>9 to our industry observers --</p> <p>10 QUESTIONS BY MR. BOWDEN:</p> <p>11 Q. Right.</p> <p>12 A. -- which were Dr. Muscat and</p> <p>13 Dr. Gunter Oberdörster.</p> <p>14 Q. Right.</p> <p>15 A. We brought things to their</p> <p>16 attention that we would be important to the</p> <p>17 deliberations of the working group.</p> <p>18 Q. Was the intention there to</p> <p>19 influence the proceedings?</p> <p>20 A. The intention was to provide</p> <p>21 them information from which they could make a</p> <p>22 reasoned, scientific decision.</p> <p>23 Q. Do you agree with my statement</p> <p>24 that the intention was to influence the</p> <p>25 proceedings?</p>	<p>1 would be the CTFA, right? They had input?</p> <p>2 A. I don't recall. They may have.</p> <p>3 Q. IMA-North America?</p> <p>4 A. IMA-North America did. In</p> <p>5 fact, they sponsored Dr. Muscat. A Euro talc</p> <p>6 sponsored Dr. Oberdörster.</p> <p>7 Q. IMA-North America sponsored</p> <p>8 Dr. Muscat, right?</p> <p>9 A. They underwrote his expenses to</p> <p>10 IARC.</p> <p>11 Q. Right.</p> <p>12 And they underwrote it, they</p> <p>13 estimated the combined total for both</p> <p>14 observers to be about \$100,000 to the group.</p> <p>15 And the question was, how were they going to</p> <p>16 pay for it, right?</p> <p>17 MR. HEGARTY: Objection. Form.</p> <p>18 THE WITNESS: I don't recall</p> <p>19 that, that discussion or that</p> <p>20 documentation. I didn't see it in</p> <p>21 preparing for here today.</p> <p>22 QUESTIONS BY MR. BOWDEN:</p> <p>23 Q. Sure. And I understand that.</p> <p>24 But that's -- that's -- your</p> <p>25 expectation is that -- the industry's</p>
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<p>1 MR. HEGARTY: Objection. Form.</p> <p>2 MR. DONATH: Objection. Form.</p> <p>3 THE WITNESS: We had opinions</p> <p>4 on -- scientific opinions on that, and</p> <p>5 certainly we wanted to put those</p> <p>6 forward to the working group.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. With the intent to influence</p> <p>9 the working group's thought process and</p> <p>10 discussion?</p> <p>11 MR. HEGARTY: Objection. Form.</p> <p>12 MR. DONATH: Same objection.</p> <p>13 THE WITNESS: We wanted -- they</p> <p>14 were going to vote on their own, but</p> <p>15 we wanted to make them aware of</p> <p>16 certain things that they should take</p> <p>17 into consideration and that certainly</p> <p>18 were our opinions on the science.</p> <p>19 QUESTIONS BY MR. BOWDEN:</p> <p>20 Q. Right.</p> <p>21 A. They were our opinions, and we</p> <p>22 wanted to get those in front of IARC and have</p> <p>23 them treat them as any scientific input.</p> <p>24 Q. So in the industry, the trade</p> <p>25 groups that we're talking about here, that</p>	<p>1 expectation, it costs about \$50,000 to have</p> <p>2 an observer go over there and participate in</p> <p>3 the proceedings?</p> <p>4 MR. DAVANT: Objection to form.</p> <p>5 MR. BILLINGS-KANG: Objection</p> <p>6 to form.</p> <p>7 THE WITNESS: Yes, to prepare</p> <p>8 and participate.</p> <p>9 QUESTIONS BY MR. BOWDEN:</p> <p>10 Q. Is that a yes?</p> <p>11 MR. BILLINGS-KANG: Objection</p> <p>12 to form.</p> <p>13 THE WITNESS: Yes, to prepare</p> <p>14 and participate.</p> <p>15 QUESTIONS BY MR. BOWDEN:</p> <p>16 Q. Did Dr. Muscat ever complain to</p> <p>17 you about not being paid?</p> <p>18 A. I don't recall that he did.</p> <p>19 Q. That he complained? You don't</p> <p>20 recall that he complained?</p> <p>21 A. I don't recall that he did.</p> <p>22 Q. Okay. Did Dr. Muscat ever</p> <p>23 complain to you about not being paid by</p> <p>24 Meta-Analysis Research Group?</p> <p>25 A. I don't recall that either.</p>

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<p>1 Q. Did he ever complain about not 2 being paid as the carve-out retainer pursuant 3 to the original agreement of \$3,000 and 4 \$3,000?</p> <p>5 MR. HEGARTY: Objection. Form.</p> <p>6 THE WITNESS: I don't recall 7 that. I don't recall him contacting 8 me at all about nonpayment for his 9 work.</p> <p>10 QUESTIONS BY MR. BOWDEN:</p> <p>11 Q. Was he paid?</p> <p>12 A. I don't know.</p> <p>13 MR. HEGARTY: Objection. Form.</p> <p>14 QUESTIONS BY MR. BOWDEN:</p> <p>15 Q. Was he paid at the IARC 16 proceedings?</p> <p>17 A. I don't know. He was paid from 18 Crowell &amp; Moring for what he did and what he 19 proposed to do. I was not involved in the 20 IMA-NA.</p> <p>21 Q. He was paid by Crowell &amp; Moring 22 for the work he did at IARC?</p> <p>23 MR. HEGARTY: Objection. Form.</p> <p>24 THE WITNESS: No, for the work 25 he did in preparing the report and</p>	<p>1 Johnson?</p> <p>2 A. I don't recall anyone from 3 Johnson &amp; Johnson being there.</p> <p>4 Q. I'm asking.</p> <p>5 A. No.</p> <p>6 Q. I'm asking. You don't recall?</p> <p>7 A. No.</p> <p>8 Q. Luzenac was there?</p> <p>9 A. Yes, Eric Turner, yes.</p> <p>10 Q. Right.</p> <p>11 Dr. Huncharek and Muscat were 12 there?</p> <p>13 A. Dr. Muscat was. Dr. Huncharek 14 was not.</p> <p>15 Q. So Dr. Huncharek just assisted 16 via e-mail and collaboration by telephone?</p> <p>17 A. That's correct.</p> <p>18 MR. HEGARTY: Objection. Form.</p> <p>19 QUESTIONS BY MR. BOWDEN:</p> <p>20 Q. Okay. And IMA-Europe was there 21 as well?</p> <p>22 A. IMA-Europe I don't -- they 23 didn't have a staff member there.</p> <p>24 Q. Okay. But the president of 25 IMA-Europe at the time, Michele --</p>
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<p>1 also in assisting Dr. Muscat on the 2 meta-analysis paper.</p> <p>3 QUESTIONS BY MR. BOWDEN:</p> <p>4 Q. I see.</p> <p>5 So the report that you're 6 referencing is, of course, the NTP report 7 that now is being used, the data from that is 8 being used, at the IARC proceedings, right?</p> <p>9 A. Yes.</p> <p>10 MR. HEGARTY: Objection. Form.</p> <p>11 THE WITNESS: It was, yes.</p> <p>12 QUESTIONS BY MR. BOWDEN:</p> <p>13 Q. IARC work group met in February 14 of 2006, right?</p> <p>15 A. Yes.</p> <p>16 Q. And when you went over there, 17 you went over there with a number of people 18 to have a support team on the ground --</p> <p>19 A. That's correct.</p> <p>20 Q. -- true?</p> <p>21 A. Yes.</p> <p>22 Q. And those support team members 23 consisted of yourself?</p> <p>24 A. Yes.</p> <p>25 Q. A representative from Johnson &amp;</p>	<p>1 A. Wyart-Remy.</p> <p>2 Q. Uh-huh.</p> <p>3 She was involved on a daily 4 basis, right?</p> <p>5 A. Through e-mails and such, yes.</p> <p>6 Q. Were there any oncologists 7 involved on the industry's behalf?</p> <p>8 A. No.</p> <p>9 Q. Any gynecologists involved on 10 the industry's behalf?</p> <p>11 A. No.</p> <p>12 Q. What about the CTFA?</p> <p>13 A. They were not at the meeting.</p> <p>14 Q. But Linda Loretz, she 15 participated, right?</p> <p>16 A. She likely did through e-mails.</p> <p>17 Q. Okay. And just to make sure 18 that the jury understands what we're 19 describing here, the industry knew that the 20 issue was going to be taken up at the IARC 21 proceedings, fair?</p> <p>22 A. Yes. Yes, the industry knew.</p> <p>23 Q. Months and months of 24 preparation went into those proceedings on 25 behalf of the industry, right?</p>

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<p>1 MR. HEGARTY: Objection. Form. 2 MR. DONATH: Objection to form. 3 MR. BILLINGS-KANG: Objection. 4 Form. 5 THE WITNESS: I don't know 6 about months and months, but, yeah, it 7 was over a long period of time, but it 8 wasn't constant. 9 QUESTIONS BY MR. BOWDEN: 10 Q. Okay. And -- well, let's talk 11 about that. 12 I want to talk to you first 13 about the observer nomination process. 14 A. Yes. 15 Q. Are you familiar with the 16 observer nomination process? 17 A. Not terribly familiar, no. 18 Q. Okay. Well, you know as a 19 general sequence of events -- 20 A. Oh, for observers? 21 Q. Yes, sir. I'm sorry. 22 A. Oh, I thought you meant working 23 group. 24 Q. No, sir, I'm talking about 25 observers.</p>	<p>1 Q. And in fact, because of the way 2 the organizations worked out, he also ended 3 up being the president of the National 4 Industrial Sand Association as well, right? 5 A. Yes. National Industrial Sand 6 Association continued to exist after the 7 formation of IMA-NA. 8 Q. Right. 9 And so Mark Ellis, in this 10 January 13th e-mail, he is forwarding to a 11 number of people -- you see Mike Larson, 12 Minerals Tech? 13 A. Yes. 14 Q. And Minerals Tech is what type 15 of company? 16 A. They're a talc company with 17 deposits in Montana. 18 Q. Uh-huh. And you see R. Price 19 from RT Vanderbilt? 20 A. This is in the "to"? 21 Q. Yes, sir. 22 A. Yeah, Price. 23 Q. RT Vanderbilt. 24 A. Yeah. Or is he a cc? 25 Q. He's in the "to" line. I've</p>
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<p>1 A. Yes, I am aware. 2 Q. And observers serve a role 3 of -- back up. 4 Industry is not allowed to 5 participate directly in the proceedings, 6 right? 7 A. They are not allowed to vote. 8 They aren't involved in the voting. At times 9 they are allowed to speak during the working 10 group sessions. 11 Q. Uh-huh. 12 A. They play a limited role. 13 (Glenn Exhibit 19 marked for 14 identification.) 15 QUESTIONS BY MR. BOWDEN: 16 Q. I believe I'm on Exhibit 17 Number 19. 18 Here you go, sir. 19 Yours is marked as 19? 20 A. Yes. Thank you. 21 Q. You had mentioned Mark Ellis 22 previously. He was actually the president of 23 IMA-North America at the time of the IARC 24 proceedings, right? 25 A. Yes.</p>	<p>1 got it highlighted on the screen here for 2 you. 3 A. Oh, okay. 4 Q. RT Vanderbilt. That's another 5 talc manufacturer, right? 6 A. Yes, an industrial talc. 7 Q. And you see V. Sadowski right 8 after him, the next line down, from Zemex? 9 A. Yes. 10 Q. And that's another talc 11 manufacturer? 12 A. Yes. 13 Q. And you see Luzenac listed 14 there as well, right? 15 A. Yes. 16 Q. And you are listed as the last 17 person on that e-mail chain, right? 18 A. Yes. 19 Q. Copied on this is Steven Mann, 20 Johnson &amp; Johnson? 21 A. Yes. 22 Q. You've got Linda Loretz from 23 CTFA? 24 A. Yes. 25 Q. And you've got Ed deBeus from</p>



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<p>1 Mondo Minerals, right?</p> <p>2 A. Yes.</p> <p>3 Q. And that's another talc</p> <p>4 interested party?</p> <p>5 A. I don't know him, but that's a</p> <p>6 European talc company.</p> <p>7 Q. Uh-huh. And you've also got</p> <p>8 Josh Muscat on there, right?</p> <p>9 A. Yes, I guess. Yeah.</p> <p>10 Q. And in this e-mail chain, do</p> <p>11 you see any consumer groups represented?</p> <p>12 A. What do you mean by "consumer</p> <p>13 groups"? Is the CTFA on there?</p> <p>14 Q. Well, that's an industry group,</p> <p>15 right?</p> <p>16 A. Well, they -- they provide</p> <p>17 downstream products to consumers.</p> <p>18 Q. Well, I'm not talking about the</p> <p>19 companies that make something that they sell</p> <p>20 to consumers.</p> <p>21 A. Okay.</p> <p>22 Q. I'm talking about consumers --</p> <p>23 A. Yeah, they're -- they are a</p> <p>24 trade organization.</p> <p>25 Q. Right.</p>	<p>1 Q. Yeah.</p> <p>2 "IARC appreciates the interest</p> <p>3 of all parties have" -- excuse me, strike</p> <p>4 that.</p> <p>5 "IARC appreciates the interest</p> <p>6 all parties have in seeing that monographs</p> <p>7 are the outcome of a rigorous scientific</p> <p>8 assessment free of any attempt at</p> <p>9 interference."</p> <p>10 Do you see that, the first --</p> <p>11 A. Yes.</p> <p>12 Q. "These guidelines are meant to</p> <p>13 convey a common understanding of conduct</p> <p>14 expected from observers at IARC monograph</p> <p>15 meetings."</p> <p>16 A. Yes.</p> <p>17 Q. This was shared with</p> <p>18 Dr. Muscat, right? He's one of the e-mail</p> <p>19 recipients?</p> <p>20 A. Yes. Yes.</p> <p>21 Q. As well as Dr. Oberdörster,</p> <p>22 correct?</p> <p>23 A. Yes.</p> <p>24 Q. Those are the two IARC -- or</p> <p>25 excuse me, industry observers that were being</p>
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<p>1 So consumer groups, they're not</p> <p>2 on this e-mail chain. Consumers, I'm sorry,</p> <p>3 consumers are not --</p> <p>4 A. Consumers are not, yeah.</p> <p>5 Q. Right. Right.</p> <p>6 What about medical societies?</p> <p>7 A. No, there are no medical</p> <p>8 societies.</p> <p>9 Q. Okay. Attached to this are the</p> <p>10 observer guidelines.</p> <p>11 Do you see that, the</p> <p>12 attachments?</p> <p>13 A. Yes.</p> <p>14 Q. We're going to go to page 61.4.</p> <p>15 A. All right.</p> <p>16 Q. You with me, sir?</p> <p>17 A. Yes.</p> <p>18 Q. And this says, "Guidelines for</p> <p>19 observers at IARC monograph meetings."</p> <p>20 A. Yes.</p> <p>21 Q. These are the -- you can see</p> <p>22 the bottom left corner says "February 2004."</p> <p>23 These were the guidelines in</p> <p>24 place at the time of the meeting?</p> <p>25 A. Yes.</p>	<p>1 put forth, right?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. "In the spirit of</p> <p>4 transparency, observers are welcome to attend</p> <p>5 IARC monograph meetings. The main role of</p> <p>6 observers is serve as sources of firsthand</p> <p>7 information from the meeting to their</p> <p>8 sponsoring organizations."</p> <p>9 Have I read that correctly?</p> <p>10 A. Yes.</p> <p>11 Q. The next paragraph down:</p> <p>12 "Implicit in the term 'observer' is the</p> <p>13 responsibility to observe," in italics.</p> <p>14 Do you see that?</p> <p>15 A. You've jumped down somewhere?</p> <p>16 Q. No, no, next paragraph, sir,</p> <p>17 the next --</p> <p>18 A. Oh.</p> <p>19 Q. Let me read it to you again.</p> <p>20 A. Yeah.</p> <p>21 Q. "Implicit in the term</p> <p>22 'observer' is the responsibility to observe</p> <p>23 the meeting and not to attempt to influence</p> <p>24 its outcome."</p> <p>25 A. Yeah, let's see. You left out</p>

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<p>1 a sentence that says --</p> <p>2 Q. Yeah, I'm not reading the whole</p> <p>3 document.</p> <p>4 A. "Also can play a valuable role</p> <p>5 in ensuring that all published information</p> <p>6 and scientific perspectives are considered."</p> <p>7 Q. Yeah, no question. They're</p> <p>8 able to walk in information, right?</p> <p>9 A. Yeah. I just wanted to bring</p> <p>10 that out.</p> <p>11 Q. Right. Well, I'm actually</p> <p>12 going to show you some documents where that's</p> <p>13 exactly what you guys did, right?</p> <p>14 A. Yes, we did.</p> <p>15 Q. Right. And that's part of the</p> <p>16 role of the observers, is to --</p> <p>17 A. To bring scientific information</p> <p>18 forward, correct.</p> <p>19 Q. Not to lobby the meeting</p> <p>20 participants, right?</p> <p>21 A. That's right.</p> <p>22 Q. And you're not supposed to be</p> <p>23 trying to influence its outcome, and that</p> <p>24 includes both before and during the meeting,</p> <p>25 right?</p>	<p>1 Do you see that?</p> <p>2 A. Yeah.</p> <p>3 Q. And you're aware that</p> <p>4 Dr. Muscat is cited in the monograph as an</p> <p>5 observer, right?</p> <p>6 A. Yes.</p> <p>7 Q. Have you read the 93 monograph?</p> <p>8 A. It's been some time. I think</p> <p>9 it's 400 pages or something.</p> <p>10 Q. 496, yeah.</p> <p>11 A. That's close.</p> <p>12 Q. I didn't print them all out for</p> <p>13 us, but I want to show you this page.</p> <p>14 Okay?</p> <p>15 A. Okay.</p> <p>16 (Glenn Exhibit 20 marked for</p> <p>17 identification.)</p> <p>18 QUESTIONS BY MR. BOWDEN:</p> <p>19 Q. This is Exhibit Number 20.</p> <p>20 Now, following this 2006</p> <p>21 working group, 2006 working group, the</p> <p>22 monograph itself was actually published in</p> <p>23 2010 --</p> <p>24 A. Correct.</p> <p>25 Q. -- correct?</p>
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<p>1 A. Oh, okay. Not to lobby</p> <p>2 participants. Yeah.</p> <p>3 Q. Okay.</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And at the bottom it</p> <p>6 says, "Observers will complete a</p> <p>7 declaration."</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. "Observers will complete a</p> <p>11 declaration of interests that covers</p> <p>12 financial interest" -- that's payments?</p> <p>13 A. Yes.</p> <p>14 Q. "Employment interests,</p> <p>15 including consulting or other affiliations"?</p> <p>16 A. Correct.</p> <p>17 Q. "And research support, whether</p> <p>18 granted to the individual or an affiliated</p> <p>19 organization."</p> <p>20 Right?</p> <p>21 A. Yes.</p> <p>22 Q. "Interests pertinent to the</p> <p>23 subject matter of the meeting will be</p> <p>24 disclosed to the meeting participants and</p> <p>25 published in the monograph."</p>	<p>1 A. Yes.</p> <p>2 Q. But the time that the industry</p> <p>3 observers were participating was February</p> <p>4 of 2006 --</p> <p>5 A. Yes.</p> <p>6 Q. -- correct?</p> <p>7 So I want you to turn to the</p> <p>8 second page of this document.</p> <p>9 A. Yes.</p> <p>10 Q. And do you see where it has</p> <p>11 participants and it lists observers, right?</p> <p>12 A. Yes.</p> <p>13 Q. Just like we saw was going to</p> <p>14 happen on the declaration of -- or excuse me,</p> <p>15 the observer guidelines, right?</p> <p>16 A. Yes.</p> <p>17 Q. And they're required to</p> <p>18 disclose financial interests, including</p> <p>19 funding, at the time, right?</p> <p>20 A. That is likely through a form</p> <p>21 they submit to IARC.</p> <p>22 Q. I've got the form.</p> <p>23 A. Okay. I haven't seen it.</p> <p>24 Q. Okay.</p> <p>25 A. All right. Yes.</p>

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<p>1 Q. "Observers sponsored by the 2 Industrial Minerals Association of Europe and 3 of North America," right? 4 A. Yes. 5 Q. And it lists Josh Muscat? 6 A. Yes. 7 Q. And so Josh Muscat, I think 8 before you said that he was only sponsored by 9 IMA-North America, but here he's saying that 10 he's sponsored by IMA-Europe and of North 11 America, right? 12 A. Let me see. They paid his 13 freight, yes. IMA, they paid for him to go 14 over. 15 Q. IMA-Europe and of North 16 America, right? 17 A. No, IMA-North America -- 18 Q. Okay. 19 A. -- is my understanding of what 20 I believed happened. 21 Q. Sure. 22 It says, Josh E. Muscat -- 23 "Joshua E. Muscat, Department of Health 24 Evaluation Sciences, Pennsylvania State of 25 College of Medicine, Hershey, Pennsylvania,</p>	<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. Doesn't list Meta-Analysis 3 Research Group, right? 4 MR. BILLINGS-KANG: Objection. 5 Asked and answered. 6 THE WITNESS: No, he does not. 7 QUESTIONS BY MR. BOWDEN: 8 Q. Doesn't list Crowell &amp; Moring? 9 A. No. 10 Q. Doesn't list Imerys? 11 A. No. 12 Q. During that time, Imerys was 13 directly funding the diaphragm study, true? 14 MR. DONATH: Objection. Form. 15 MR. HEGARTY: Objection. Form. 16 THE WITNESS: We funded that 17 study, and it was probably running 18 through this period as well. 19 QUESTIONS BY MR. BOWDEN: 20 Q. J&amp;J was also supporting that 21 study at the time that the IARC working group 22 meeting went on, true? 23 MR. DONATH: Objection to form. 24 MR. HEGARTY: Objection. Form. 25 THE WITNESS: He's serving as</p>
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<p>1 USA," right? 2 A. Right. 3 Q. It doesn't say Meta-Analysis 4 Research Group? 5 A. No. 6 Q. But during that time, he was 7 underneath a contract with Crowell &amp; Moring 8 as a part of Meta-Analysis Research Group, 9 correct? 10 A. I think he was paid -- 11 MR. HEGARTY: Objection. Form. 12 THE WITNESS: He was paid 13 partly for his work, \$3,000 or 14 something. 15 QUESTIONS BY MR. BOWDEN: 16 Q. My question to you is that at 17 this time, he was underneath a contract with 18 Meta-Analysis Research Group to perform 19 services for Crowell &amp; Moring on behalf of 20 their talc client, correct? 21 MR. HEGARTY: Objection. Form. 22 MR. DONATH: Objection. Form. 23 THE WITNESS: Yes, he listed 24 his primary employer here, which was 25 the university.</p>	<p>1 an industry observer, not an observer 2 for Crowell &amp; Moring or J&amp;J or anyone 3 else. He's acting as observant to the 4 larger industrial minerals talc 5 industry. 6 QUESTIONS BY MR. BOWDEN: 7 Q. So now what we're doing here is 8 we've got a split screen. One is from the 9 monograph 93, right? 10 A. Okay. 11 Q. And you can see the top is what 12 we just covered. That's the one that 13 discloses the industry observers and who 14 they're participating on behalf of, right? 15 A. Yes. Yeah. 16 Q. And the bottom is what we 17 covered with the industry observer 18 guidelines, true? 19 A. Yes. 20 Q. That's from 61.4? 21 A. Right. 22 Q. Let's read this again. 23 "Observer will complete a declaration of 24 interest that covers financial interest, 25 employment interest, including consulting and</p>

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<p style="text-align: right;">Page 246</p> <p>1 other affiliations," right?</p> <p>2 A. Yes.</p> <p>3 Q. Do you see anywhere in that</p> <p>4 above block quote where Dr. Muscat discloses</p> <p>5 the consulting work that he is doing with</p> <p>6 MRG, Johnson &amp; Johnson, Luzenac or Crowell &amp;</p> <p>7 Moring, the law firm?</p> <p>8 A. He did not.</p> <p>9 MR. DAVANT: Object to form.</p> <p>10 THE WITNESS: According to what</p> <p>11 the others did, he should have listed</p> <p>12 that.</p> <p>13 MR. BOWDEN: Take that down,</p> <p>14 please.</p> <p>15 (Glenn Exhibit 21 marked for</p> <p>16 identification.)</p> <p>17 QUESTIONS BY MR. BOWDEN:</p> <p>18 Q. I want to go back to --</p> <p>19 actually, it's going to be a new document.</p> <p>20 I'm going to tell you right now</p> <p>21 that we're going backwards, back to October</p> <p>22 of 2005.</p> <p>23 A. Okay.</p> <p>24 Q. Okay?</p> <p>25 A. All right.</p>	<p style="text-align: right;">Page 248</p> <p>1 Luzenac America; IMA -- that's Michele Wyart.</p> <p>2 That's going to be IMA-Europe, right?</p> <p>3 A. Yes, yes, it would be.</p> <p>4 Q. And then Ms. Abrams, who's an</p> <p>5 attorney, right?</p> <p>6 A. Yes. Yes.</p> <p>7 Q. And so if we turn to the second</p> <p>8 page here, 68.2, it's going to be bullet</p> <p>9 point number 10, it says, "The group</p> <p>10 discussed the IARC talc project and</p> <p>11 recommendations for an industry observer."</p> <p>12 Do you see where that's</p> <p>13 happening?</p> <p>14 A. Yes.</p> <p>15 Q. And this group, again, we just</p> <p>16 kind of run through them, those are some of</p> <p>17 the talc manufacturers, right?</p> <p>18 A. Yes.</p> <p>19 Q. Including Luzenac, your client?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. "Potential observers are</p> <p>22 Joshua Muscat of Penn State and Michael</p> <p>23 Huncharek of St. Michaels Hospital, Stevens</p> <p>24 Point, Wisconsin.</p> <p>25 Do you see that?</p>
<p style="text-align: right;">Page 247</p> <p>1 Q. So we're kind of covering</p> <p>2 things a little bit linearly, but now we're</p> <p>3 doing it by topic.</p> <p>4 A. Okay.</p> <p>5 Q. You see here that this is the</p> <p>6 minutes of the talc section at IMA-North</p> <p>7 America.</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. And it appears that there was a</p> <p>11 meeting that took place at the Plaza Hotel,</p> <p>12 or the Avance Plaza Hotel in Washington, DC.</p> <p>13 A. Yes.</p> <p>14 Q. Have you ever been there</p> <p>15 before?</p> <p>16 A. Yes.</p> <p>17 Q. Were you at this meeting?</p> <p>18 A. Pardon?</p> <p>19 Q. Were you at this meeting?</p> <p>20 A. No. No, I don't think so.</p> <p>21 This was after I left.</p> <p>22 Q. Is it a nice hotel?</p> <p>23 A. It's fairly nice.</p> <p>24 Q. Meeting participants:</p> <p>25 Specialty Minerals, chairman; RT Vanderbilt;</p>	<p style="text-align: right;">Page 249</p> <p>1 A. Yes.</p> <p>2 Q. And ultimately they rejected</p> <p>3 Dr. Muscat as an observer, didn't they, or</p> <p>4 did you decide not to nominate him?</p> <p>5 A. I don't recall that.</p> <p>6 Q. So it wasn't IARC that rejected</p> <p>7 him; the group said not to put him up?</p> <p>8 MR. HEGARTY: Objection. Form.</p> <p>9 THE WITNESS: I'm not sure</p> <p>10 where you're going.</p> <p>11 QUESTIONS BY MR. BOWDEN:</p> <p>12 Q. I'm asking you, was</p> <p>13 Dr. Huncharek ever proposed --</p> <p>14 MR. DONATH: You said Muscat.</p> <p>15 THE WITNESS: Oh, Huncharek. I</p> <p>16 thought you -- I was thinking of</p> <p>17 Muscat.</p> <p>18 MR. BOWDEN: Oh, I apologize.</p> <p>19 Everyone is telling me I'm wrong.</p> <p>20 I'll go with -- I'm sorry, let me</p> <p>21 reword that.</p> <p>22 QUESTIONS BY MR. BOWDEN:</p> <p>23 Q. Dr. Huncharek did not become an</p> <p>24 industry observer?</p> <p>25 A. Yes, he did not.</p>

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<p>1 Q. Okay. Why not?</p> <p>2 A. Because they -- IARC only</p> <p>3 allowed two.</p> <p>4 Q. Right.</p> <p>5 A. So IMA-Europe got one and</p> <p>6 IMA-North America got one.</p> <p>7 Q. Right. And Dr. Hun -- or</p> <p>8 Muscat was the one that was proposed for --</p> <p>9 was it the epi subgroup?</p> <p>10 A. I believe so, yes.</p> <p>11 Q. Right.</p> <p>12 And it continues on: "The</p> <p>13 group agreed to contact Michael Huncharek on</p> <p>14 a motion by Michele Wyart."</p> <p>15 That's the IMA-Europe</p> <p>16 president, right?</p> <p>17 A. Yeah.</p> <p>18 Q. "Bob Glenn and Mark Ellis will</p> <p>19 be asked to make the contact."</p> <p>20 Do you see that there?</p> <p>21 A. Yes.</p> <p>22 Q. And Mark Ellis being the</p> <p>23 president of IMA-North America, and Bob</p> <p>24 Glenn, of course, is you, the former</p> <p>25 president, right?</p>	<p>1 Q. Okay.</p> <p>2 A. Probably -- probably when I was</p> <p>3 still at Crowell &amp; Moring. So I don't think</p> <p>4 I've had contact with him since 2010.</p> <p>5 Q. Do you know that he's a</p> <p>6 fugitive right now?</p> <p>7 MR. DONATH: Objection. Form.</p> <p>8 MR. HEGARTY: Objection. Form.</p> <p>9 THE WITNESS: No, I did not</p> <p>10 know that.</p> <p>11 QUESTIONS BY MR. BOWDEN:</p> <p>12 Q. Does that surprise you?</p> <p>13 A. Well, I don't know the details,</p> <p>14 but it wouldn't surprise me.</p> <p>15 Q. All right. Now, after you</p> <p>16 reached out to Dr. Muscat to propose -- to</p> <p>17 have himself-nominate, right?</p> <p>18 A. Yes.</p> <p>19 MR. DONATH: Objection.</p> <p>20 THE WITNESS: No, the industry</p> <p>21 sent his name in.</p> <p>22 QUESTIONS BY MR. BOWDEN:</p> <p>23 Q. The industry sent his name in;</p> <p>24 you just had the contact with him?</p> <p>25 A. Pardon?</p>
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<p>1 A. Yes. Yes.</p> <p>2 Q. Okay. And you did that, right?</p> <p>3 A. I assume we did, yes.</p> <p>4 Q. And at this point in time in</p> <p>5 2005, your only employer is the Crowell &amp;</p> <p>6 Moring law firm, right?</p> <p>7 A. Right.</p> <p>8 Q. Okay. Were you paid by</p> <p>9 Crowell &amp; Moring to make that contact?</p> <p>10 A. To --</p> <p>11 Q. To Dr. Muscat?</p> <p>12 A. I doubt it. It was probably a</p> <p>13 telephone call. And I'm not sure I did it or</p> <p>14 Mark did it.</p> <p>15 Q. Okay. Do you know where</p> <p>16 Dr. Huncharek is right now?</p> <p>17 A. The last I knew of him, and I</p> <p>18 haven't had contact with him, he was at the</p> <p>19 University of South Carolina School of Public</p> <p>20 Health.</p> <p>21 Q. Okay. And when was the last</p> <p>22 time you spoke with him?</p> <p>23 A. It's been a long time ago.</p> <p>24 Q. Are you talking about years?</p> <p>25 A. Yeah.</p>	<p>1 MR. DONATH: Objection.</p> <p>2 QUESTIONS BY MR. BOWDEN:</p> <p>3 Q. You had the contact with him?</p> <p>4 MR. DONATH: Objection. Form.</p> <p>5 THE WITNESS: I don't know</p> <p>6 whether I did or Mark. It was</p> <p>7 probably Mark because he was</p> <p>8 representing IMA-North America.</p> <p>9 QUESTIONS BY MR. BOWDEN:</p> <p>10 Q. I see.</p> <p>11 Okay. And you remained</p> <p>12 involved in helping the industry observers</p> <p>13 prepare for their participation at IARC,</p> <p>14 right?</p> <p>15 A. Yes, I did.</p> <p>16 Q. In fact, you actually had</p> <p>17 conducted presentations, right?</p> <p>18 A. Yes, I have. I did.</p> <p>19 Q. And those preparations -- how</p> <p>20 many days did that take place over?</p> <p>21 A. One day. The one day, and</p> <p>22 probably half a day.</p> <p>23 Q. Half a day?</p> <p>24 A. Yeah.</p> <p>25 Q. Was it just you presenting?</p>

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<p>1 A. I presented on talc. It was a 2 group re -- it was a group that was involved 3 with the carbon black industry, titanium 4 dioxide industry, and talc, and we were 5 sharing kind of the basic knowledge of our 6 agent, our substance. 7 Q. I apologize for coughing during 8 your statement there. 9 But I understand that the IARC 10 proceeding, it wasn't just on talc, it was 11 also on carbon black? 12 A. Correct. 13 Q. And titanium dioxide? 14 A. Yes. 15 Q. Okay. And the proceeding 16 you're talking about, the half-day 17 presentation that you gave, that actually 18 took place down at Puerto Rico, right? 19 A. That's right. 20 Q. Why did it take place in Puerto 21 Rico? 22 A. There was a meeting of 23 occupational physicians that was held the 24 previous two days or so, and we took one 25 afternoon, as I recall, for these groups to</p>	<p>1 meeting took place. 2 Q. Right. And so now we've been 3 talking about how long the industry has been 4 preparing for the IARC meeting. We've seen 5 documents that went back to October? 6 A. Yes. 7 Q. And efforts took place before 8 then, too, right? 9 A. Yes. 10 Q. Because by August, you knew 11 that they were going to be taking a look at 12 the issue, right? 13 A. No. Once we knew that they 14 were going to review talc, we started our -- 15 developing our message, if you will. 16 Q. Okay. And one of the things 17 that you were doing in Puerto Rico was you 18 were giving this presentation to the 19 observers? 20 A. Yes, to the industry observers 21 from all groups, although Dr. -- I don't 22 believe Dr. Muscat or Dr. Huncharek were 23 there. 24 Q. You don't think they were 25 there?</p>
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<p>1 get together and talk about their substance. 2 (Glenn Exhibit 22 marked for 3 identification.) 4 QUESTIONS BY MR. BOWDEN: 5 Q. Okay. Can we go ahead and put 6 up his -- this is Exhibit 22. 7 You recognize this, right? 8 A. Yes, I do. 9 MR. DONATH: Do you have 10 another copy? 11 MR. BOWDEN: I apologize. I 12 thought I handed them -- I might have 13 one more. 14 QUESTIONS BY MR. BOWDEN: 15 Q. All right. You recognize this 16 PowerPoint. This is the one that you put 17 together, right? 18 A. Yes. 19 Q. Okay. And it's entitled 20 "Non-Asbestiform Talc Overview," right? 21 A. Yes. 22 Q. IARC monograph 93 observers 23 meetings, San Juan, Puerto Rico, January 12, 24 2006. Right? 25 A. Correct. That's the date the</p>	<p>1 A. I don't think they were. 2 Q. Is there anything in this 3 document -- have you reviewed this 4 document -- 5 A. Yes, I looked over it. 6 Q. -- in preparing for your 7 deposition? 8 A. Yes. 9 Q. Was there anything in this 10 document that was inconsistent with the 11 messages that you gave to Dr. Muscat prior to 12 him participating as an industry observer? 13 MR. HEGARTY: Objection. Form. 14 THE WITNESS: I mean, we went 15 through more than just this, possibly, 16 and gave him more papers and things to 17 read, but essentially this was the 18 thrust -- 19 QUESTIONS BY MR. BOWDEN: 20 Q. Right. 21 A. -- of the comment, yeah. 22 Q. All right. So this was the 23 thrust of the comment, to bring people like 24 Dr. Ober -- 25 A. Oberdörster.</p>

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<p style="text-align: right;">Page 258</p> <p>1 Q. -- Oberdörster up to speed on 2 the talc issue that might not necessarily be 3 directly related to talc? 4 A. Yeah, and actually for 5 Dr. Morfeld, who was an observer for, I 6 believe, titanium dioxide. 7 So we were trying to get the 8 whole group attuned to these things so as 9 they sat through meetings, they could come up 10 with something as well that we might want to 11 look further into. 12 Q. Right. 13 A. It wasn't just talc group. 14 Q. I'm sorry? 15 A. Just wasn't talc observers. 16 All observers. 17 Q. And I -- I'm not trying to give 18 you the impression that it was only to -- 19 A. Okay. All right. 20 Q. -- educate the talc observers. 21 A. Sure. 22 Q. What this does, though, and if 23 we flip to the first page -- the second page, 24 excuse me, at the top you're going to find 25 that on every single one of these pages it</p>	<p style="text-align: right;">Page 260</p> <p>1 MR. HEGARTY: Objection. Form. 2 THE WITNESS: It was a request 3 of all agents that were being 4 reviewed, titanium dioxide and carbon 5 black. 6 Someone came up with the idea 7 that this meeting was taking place in 8 Puerto Rico, some of these other 9 observers were going to be there, and 10 it made sense to do it in that place. 11 So I went to the meeting for that 12 purpose. 13 QUESTIONS BY MR. BOWDEN: 14 Q. And you were appearing on 15 behalf of Imerys? 16 MR. DONATH: Objection. Form. 17 THE WITNESS: I was -- yes, 18 I -- Imerys would have been paying me 19 for this. 20 QUESTIONS BY MR. BOWDEN: 21 Q. All right. Let's go to -- 22 MR. BOWDEN: Mr. Smith, these 23 pages are not numbered, but it would 24 be the third page. The title is 25 "Asbestos and Talc."</p>
<p style="text-align: right;">Page 259</p> <p>1 says "Crowell &amp; Moring," right? 2 A. Yes. 3 Q. Did the attorneys help prepare 4 this? 5 A. No. 6 Q. This was all you? 7 A. This is all me. 8 Q. On behalf of Crowell &amp; Moring? 9 A. I don't think there's any 10 attorney input into this. 11 Q. Okay. This was part of the 12 message that you expected the industry to put 13 forth -- 14 A. This is the scientific opinions 15 of Bob Glenn and how he formed those 16 opinions. 17 Q. Right. 18 A. Pretty much. There was more 19 than that, but this is distilling it down 20 into 15 or 20 minutes that I might have had 21 for a presentation. 22 Q. Sure. 23 And this message that you 24 delivered, this was at the request of the 25 IMA-North America?</p>	<p style="text-align: right;">Page 261</p> <p>1 QUESTIONS BY MR. BOWDEN: 2 Q. "The notion that asbestos is 3 commonly found in talc ore deposits is not 4 correct." 5 Do you see where that's 6 written? 7 A. Yes. 8 Q. And you don't list a citation 9 for that, correct? 10 A. I didn't list them for any of 11 them. I've opined on that subject in another 12 paper, though. 13 Q. Right. 14 And we're not here today to ask 15 you about your opinions. That's not what 16 you're here for, right? 17 A. Oh, okay. 18 Q. And you're not being disclosed 19 as an expert, to your knowledge, correct? 20 A. Okay. 21 Q. True? 22 A. Yes. I'm being -- I'm being 23 put up because of my work for Imerys at 24 Crowell &amp; Moring. 25 Q. Have you been retained as a</p>

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<p style="text-align: right;">Page 262</p> <p>1 litigation expert in this --</p> <p>2 A. In talc litigation?</p> <p>3 Q. Yes, sir.</p> <p>4 A. Yes.</p> <p>5 Q. By who?</p> <p>6 A. By a company, Southern Talc.</p> <p>7 Q. Okay. Reads --</p> <p>8 A. And cosmetic talc by Southern</p> <p>9 Talc.</p> <p>10 Q. Uh-huh.</p> <p>11 A. I've also been retained by</p> <p>12 Pfizer, which I mentioned earlier --</p> <p>13 Q. Okay.</p> <p>14 A. -- in industrial talc.</p> <p>15 Q. Didn't mention it earlier in</p> <p>16 the context of 2010 to 2015.</p> <p>17 Are you currently working for</p> <p>18 Pfizer?</p> <p>19 MR. DONATH: Objection.</p> <p>20 THE WITNESS: Yes. The last</p> <p>21 thing I did was last year.</p> <p>22 QUESTIONS BY MR. BOWDEN:</p> <p>23 Q. On talc?</p> <p>24 A. Yes.</p> <p>25 It may have been this year.</p>	<p style="text-align: right;">Page 264</p> <p>1 statements in his papers, his published</p> <p>2 articles?</p> <p>3 MR. HEGARTY: Objection. Form.</p> <p>4 THE WITNESS: Yeah, I think it</p> <p>5 would.</p> <p>6 QUESTIONS BY MR. BOWDEN:</p> <p>7 Q. Would it surprise you to learn</p> <p>8 that Dr. Muscat doesn't know where he got the</p> <p>9 citation from?</p> <p>10 MR. HEGARTY: Objection. Form.</p> <p>11 THE WITNESS: It would, and I</p> <p>12 don't know. I -- yeah.</p> <p>13 QUESTIONS BY MR. BOWDEN:</p> <p>14 Q. Okay. All right. We'll move</p> <p>15 on.</p> <p>16 A. Is there something incorrect</p> <p>17 with the science here?</p> <p>18 Q. Let's go on to -- I'm going to</p> <p>19 try to pull it up on the screen for you</p> <p>20 because it didn't print with numbers.</p> <p>21 A. Yeah. That would be good.</p> <p>22 Yeah.</p> <p>23 Q. Now, the message that you were</p> <p>24 giving to all industry observers was "overall</p> <p>25 strength that statistical associations</p>
<p style="text-align: right;">Page 263</p> <p>1 I'm pretty sure it was the last year, last</p> <p>2 work I did for Pfizer.</p> <p>3 Q. "The occurrence of asbestos in</p> <p>4 talc ore bodies is rare to nonexistent."</p> <p>5 Do you see where that's</p> <p>6 written?</p> <p>7 A. Yes.</p> <p>8 Q. Do you ever recall making these</p> <p>9 statements to Dr. Muscat?</p> <p>10 MR. HEGARTY: Objection. Form.</p> <p>11 THE WITNESS: No, I don't think</p> <p>12 I did.</p> <p>13 QUESTIONS BY MR. BOWDEN:</p> <p>14 Q. Okay. Fair to say that as you</p> <p>15 sit here today you don't recall all the</p> <p>16 conversations that you've had with</p> <p>17 Dr. Muscat?</p> <p>18 A. Of course not.</p> <p>19 Q. Okay. And we've mentioned</p> <p>20 before that Dr. Muscat has already had his</p> <p>21 deposition testimony taken in this</p> <p>22 litigation?</p> <p>23 A. Yeah.</p> <p>24 Q. Would it surprise you to learn</p> <p>25 that Dr. Muscat has made these same</p>	<p style="text-align: right;">Page 265</p> <p>1 observed have been weak."</p> <p>2 And again, we're talking</p> <p>3 specifically about ovarian cancer</p> <p>4 epidemiology, right?</p> <p>5 A. I wasn't -- I was informing</p> <p>6 them that this is my scientific opinion and</p> <p>7 why I feel this way.</p> <p>8 You said a message. I wasn't</p> <p>9 conveying a message. I was saying that my</p> <p>10 interpretation, my evaluation, of the</p> <p>11 science, this is what I see.</p> <p>12 Q. Okay. As you're speaking,</p> <p>13 though, you're conveying ideas to the people</p> <p>14 who are hearing it, correct?</p> <p>15 MR. DONATH: Objection. Form.</p> <p>16 THE WITNESS: Yes.</p> <p>17 QUESTIONS BY MR. BOWDEN:</p> <p>18 Q. And that's what we call</p> <p>19 communication, right?</p> <p>20 A. Well, I think -- has a</p> <p>21 different term that I would like to use.</p> <p>22 Q. Okay. I'm not going to quibble</p> <p>23 with you over the wording.</p> <p>24 A. Okay. Good.</p> <p>25 Q. But this was the message you</p>

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<p>1 were giving to the industry observers that 2 were there, true? 3 A. This is what I was informing 4 them about. 5 Q. Okay. 6 A. And I think they understood as 7 scientists that this is my scientific 8 opinions that I developed after carefully 9 reviewing the medical literature. 10 MR. BOWDEN: I move to strike 11 the second portion of the answer which 12 calls for speculation. 13 QUESTIONS BY MR. BOWDEN: 14 Q. What you write down here is 15 "the overall strength of statistical 16 associations observed have been weak." 17 Have I read that correctly? 18 A. They are. 19 Q. Generally under 2.0? 20 A. Yes. 21 Q. Mean is average of 1.3? 22 A. That's correct. 23 Q. The majority lacking 24 statistical significance? 25 A. Many did, yeah.</p>	<p>1 THE WITNESS: I wasn't, but -- 2 you know, essentially IARC agreed with 3 that, much of that. They considered 4 eight papers to be informative as to 5 whether talc is an ovarian carcinogen. 6 QUESTIONS BY MR. BOWDEN: 7 Q. Eight papers to be informative? 8 A. Yeah. 9 Q. In one of the papers they 10 rejected -- 11 MR. DAVANT: He's still not 12 done with his answer. 13 THE WITNESS: I'm talking about 14 informative in their summary. They 15 said, these are the eight papers -- I 16 think there's eight. It might have 17 been nine -- from which we can draw 18 our conclusions regarding our 19 classification of talc. 20 There were eight -- seven 21 case-control studies, and they said 22 two of them showed a relationship. 23 They said two of them are somewhat 24 uninterpretable. They said three do 25 not show a relationship.</p>
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<p>1 Q. Okay. Drs. Huncharek and 2 Dr. Muscat, they found 1.3 with statistical 3 significance. 4 You're aware of that, aren't 5 you? 6 MR. HEGARTY: Objection. Form. 7 QUESTIONS BY MR. BOWDEN: 8 Q. It's a yes or no question. 9 A. I said majority lacking. 10 Q. I'm asking whether the authors 11 who were under contracts with Crowell &amp; 12 Moring -- 13 A. The meta-analysis 1.3, and I 14 think it was statistically significant. 15 Q. Okay. That's not mentioned in 16 here, though? 17 A. Yeah. But -- yeah. 18 Q. So let me ask you: When you 19 say -- 20 MR. DAVANT: He's not done with 21 his answer. 22 QUESTIONS BY MR. BOWDEN: 23 Q. When you say "we" -- 24 MR. DAVANT: Were you finished 25 with your answer?</p>	<p>1 Further, they said that the 2 best paper was a Gertig paper, which 3 was a prospective paper and didn't 4 call for recall bias of talc. They 5 asked these nurses before they ever 6 started studying talc. 7 And that was the best paper, 8 and it failed to show an 9 exposure/response relationship. In 10 fact, it was a negative -- it was a 11 negative slope. 12 So I think while I was ahead of 13 that, that kind of supports what I was 14 saying at this meeting. 15 QUESTIONS BY MR. BOWDEN: 16 Q. Okay. So my question to you 17 was: The fact that Muscat and Huncharek 18 found statistical significance at 1.3, that's 19 not mentioned here. That was my question to 20 you. 21 MR. DONATH: Objection. Form. 22 MR. HEGARTY: Objection. Form. 23 THE WITNESS: No, and it's not 24 mentioned -- I think in litigation it 25 used to be an SMR had to be over 3</p>

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<p style="text-align: right;">Page 270</p> <p>1 before it was considered to be 2 somewhat causal. 2 to 3, something 3 might be going on, and under 2, you 4 couldn't say anything about it. 5 QUESTIONS BY MR. BOWDEN: 6 Q. You're not an attorney, are 7 you? 8 A. No. 9 Q. Then I move to strike your 10 answers. 11 A. I'm not an epidemiologist 12 either. 13 Q. Okay. Let me ask you -- and I 14 think that -- we're going to cover all this. 15 A. Okay. 16 Q. We are. 17 A. Okay. All right. 18 Q. I'm trying to move through 19 these documents because I recognize that we 20 still have material to get through, right? 21 A. Yeah. 22 Q. So my question to you -- and 23 I'm accepting that you say it is a weak 24 statistical association, right? 25 A. Yeah. The studies that are</p>	<p style="text-align: right;">Page 272</p> <p>1 QUESTIONS BY MR. BOWDEN: 2 Q. I'm asking you: When you see a 3 weak risk, that is still a risk? 4 MR. HEGARTY: Objection. Form. 5 THE WITNESS: It's -- yes, it's 6 a risk based upon the odds ratio or 7 the standard mortality ratio. 8 QUESTIONS BY MR. BOWDEN: 9 Q. Doesn't mean zero risk? 10 A. No. 11 Q. Doesn't mean no risk? 12 MR. HEGARTY: Objection to 13 form. 14 THE WITNESS: No. 15 QUESTIONS BY MR. BOWDEN: 16 Q. Would you agree with me as just 17 a general principle -- I'm not talking about 18 talc and ovarian cancer. But you would agree 19 with me that there is no acceptable risk for 20 a carcinogen? 21 MR. HEGARTY: Objection. Form. 22 MR. DONATH: Objection to form. 23 THE WITNESS: I'm not sure I 24 would agree with you on that. 25</p>
<p style="text-align: right;">Page 271</p> <p>1 informative, yes. 2 Q. And IARC says that it's a 2B 3 carcinogen. At the end of all of this -- 4 A. Right. 5 Q. -- we're going to see a 6 document that says this is a 2B carcinogen -- 7 A. That's right. 8 MR. HEGARTY: Objection. Form. 9 QUESTIONS BY MR. BOWDEN: 10 Q. -- right? 11 Which means limited evidence -- 12 A. Yeah. 13 Q. -- right? 14 I'm not quibbling with you over 15 that. 16 A. Yeah. 17 Q. My question to you is that when 18 you say "weak risk associated" -- 19 A. Yeah. 20 Q. -- that is still a risk? 21 MR. HEGARTY: Objection. Form. 22 MR. DONATH: Objection to form. 23 THE WITNESS: It's a risk. It 24 might not be significant. 25</p>	<p style="text-align: right;">Page 273</p> <p>1 QUESTIONS BY MR. BOWDEN: 2 Q. Okay. 3 A. I think we -- we accept risk to 4 carcinogens every day. 5 Q. Sure. 6 A. Sitting here right now, we're 7 probably breathing asbestos fibers. You have 8 millions in your lung. 9 MR. BOWDEN: I'm going to move 10 to strike your answer. 11 QUESTIONS BY MR. BOWDEN: 12 Q. Do you feel that there's any 13 amounts of carcinogen -- risk of carcinogen 14 that's acceptable in cosmetic products? 15 A. I don't think all carcinogens 16 are based upon alteration of DNA. I think 17 there are other processes that can take 18 place. So there can be thresholds for 19 carcinogens, in my opinion. 20 Q. Uh-huh. My question to you was 21 whether you feel that there is any level of 22 acceptable carcinogens -- 23 A. Yes. 24 Q. -- that should be present in 25 cosmetic products.</p>



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<p>1 A. In cosmetic products? I think 2 that talc is one of those. It's -- that if 3 it plays a role, it's through an inflammatory 4 process. And I'm not sure -- I don't think 5 it plays a role, but if it does, it's through 6 an inflammatory process. So there would be a 7 threshold. 8 Q. Would that be acceptable? 9 MR. HEGARTY: Objection. Form. 10 MR. DONATH: Objection to form. 11 QUESTIONS BY MR. BOWDEN: 12 Q. If true, would it be 13 acceptable? 14 A. If we knew the level. If we 15 knew the level, yes. If we knew the level, 16 that threshold level, yes, then levels below 17 that would be acceptable. 18 Q. And if you don't know the 19 level -- 20 A. Again -- 21 Q. -- do you feel it's 22 appropriate? 23 A. If you know there's DNA 24 alteration, that's a different question. I 25 don't think the genetic studies of talc have</p>	<p>1 And the other arm of the study 2 was going to be to look at human epithelial 3 ovarian cells -- 4 A. That's right. 5 Q. -- right? 6 A. That's right. 7 Q. You didn't fund the human 8 epithelial ovarian cell portion of it, did 9 you? 10 A. Yes, I think we did. 11 Q. You started it, right? 12 MR. HEGARTY: Objection. Form. 13 THE WITNESS: The epithelial 14 ovarian? It's in her report, in her 15 paper. 16 QUESTIONS BY MR. BOWDEN: 17 Q. You stopped paying it, right? 18 MR. HEGARTY: Objection. Form. 19 MR. DONATH: Objection. Form. 20 THE WITNESS: Stopped paying 21 it. She wouldn't have -- she wouldn't 22 have done the research. 23 QUESTIONS BY MR. BOWDEN: 24 Q. Oh, I'm sorry. I said 25 epithelial. Strike that. Let me get back to</p>
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<p>1 shown that the DNA adducts are formed from 2 exposure to talc. 3 Q. We're going to get -- we're 4 going to go into that. 5 You're aware that Brooke 6 Mossman and Dr. Shukla looked at this very 7 issue, right? 8 A. Yes. 9 Q. They actually brought a 10 proposal to you while you were at Crowell &amp; 11 Moring to look into this issue, right? 12 A. I asked for the proposal. 13 MR. HEGARTY: Objection to 14 form. 15 QUESTIONS BY MR. BOWDEN: 16 Q. Right. 17 And one of them was for looking 18 at what the effect of talcum particles was on 19 human mesothelial cells? 20 A. Yes. 21 Q. They were going to test 22 asbestos as well? 23 A. Yes, as a positive control, if 24 you will. 25 Q. Right.</p>	<p>1 it. 2 A. As I recall, we paid for the 3 entire study by Brooke -- well, wait a 4 minute. IMA-North America may have paid for 5 that study. That's right. It wasn't Luzenac 6 or Imerys. That study was -- I won't say any 7 more. 8 Q. If you don't know the risk, if 9 you don't know the threshold level at which 10 an agent causes cancer -- 11 A. Yes. 12 Q. -- is there any amount that's 13 acceptable in a cosmetic product? 14 MR. DAVANT: Objection to form. 15 MR. DONATH: Objection. Form. 16 THE WITNESS: In risk 17 management, we certainly accept those 18 risks. 19 QUESTIONS BY MR. BOWDEN: 20 Q. You don't know what the 21 threshold level is, how can you accept the 22 risk? 23 A. Well, do you eat -- 24 Q. It's not an opportunity for you 25 to ask me questions.</p>

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<p>1 A. All right. Well --</p> <p>2 Q. My question to you is: If you</p> <p>3 don't know what the threshold level is at</p> <p>4 which an agent can cause cancer, should you</p> <p>5 warn about it?</p> <p>6 MR. DONATH: Objection to form.</p> <p>7 THE WITNESS: As Dr. Bruce Ames</p> <p>8 pointed out, many of the things in our</p> <p>9 diet are carcinogens, and we do accept</p> <p>10 and consume those things.</p> <p>11 QUESTIONS BY MR. BOWDEN:</p> <p>12 Q. We have to eat, right?</p> <p>13 A. Yes.</p> <p>14 Q. Or we die?</p> <p>15 A. Yeah.</p> <p>16 Q. Do you have to use talcum</p> <p>17 powder?</p> <p>18 MR. DONATH: Objection. Form.</p> <p>19 THE WITNESS: You don't have</p> <p>20 to.</p> <p>21 QUESTIONS BY MR. BOWDEN:</p> <p>22 Q. So there's a different</p> <p>23 risk/benefit analysis there, right?</p> <p>24 A. Somewhat.</p> <p>25 MR. HEGARTY: Objection.</p>	<p>1 control or irritation, that's a medical usage</p> <p>2 of it.</p> <p>3 Q. People die from moisture</p> <p>4 control?</p> <p>5 A. Well, you say they might since</p> <p>6 perineal exposure leads to ovarian cancer.</p> <p>7 Q. No, people definitely do die</p> <p>8 from ovarian cancer. That's not in dispute,</p> <p>9 right?</p> <p>10 A. Yeah, they do. I agree.</p> <p>11 Q. And if something causes ovarian</p> <p>12 cancer, you want to make sure that you're,</p> <p>13 one, aware of it, right?</p> <p>14 A. Yeah.</p> <p>15 MR. DONATH: Objection. Form.</p> <p>16 QUESTIONS BY MR. BOWDEN:</p> <p>17 Q. So you can make an informed</p> <p>18 decision, true?</p> <p>19 MR. HEGARTY: Objection. Form.</p> <p>20 THE WITNESS: Yeah, the -- the</p> <p>21 American Cancer Society --</p> <p>22 MR. BOWDEN: No, focus on my</p> <p>23 question.</p> <p>24 THE WITNESS: -- does not list</p> <p>25 talc as a risk factor for ovarian</p>
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<p>1 QUESTIONS BY MR. BOWDEN:</p> <p>2 Q. Okay. So for a product which</p> <p>3 has -- personal consumer products, baby</p> <p>4 powder --</p> <p>5 A. Yeah.</p> <p>6 Q. -- has no medical necessity,</p> <p>7 right?</p> <p>8 MR. DONATH: Objection to form.</p> <p>9 THE WITNESS: Well, it's the</p> <p>10 same mineral issues in pleurodesis, so</p> <p>11 it does have medical --</p> <p>12 QUESTIONS BY MR. BOWDEN:</p> <p>13 Q. That's not my question.</p> <p>14 My question is whether</p> <p>15 talcum-based baby powders, whether they serve</p> <p>16 a medical purpose, a necessary medical</p> <p>17 purpose; yes or no?</p> <p>18 MR. DONATH: Objection to form.</p> <p>19 MR. BILLINGS-KANG: Objection.</p> <p>20 Form.</p> <p>21 THE WITNESS: Perineal</p> <p>22 application?</p> <p>23 QUESTIONS BY MR. BOWDEN:</p> <p>24 Q. Right.</p> <p>25 A. Yeah, if it's used for moisture</p>	<p>1 cancer.</p> <p>2 QUESTIONS BY MR. BOWDEN:</p> <p>3 Q. Right.</p> <p>4 Where does Dr. Mossman work,</p> <p>5 Brooke Mossman?</p> <p>6 A. University of Vermont.</p> <p>7 Q. Right.</p> <p>8 Have you been on their website</p> <p>9 recently?</p> <p>10 A. No, I have not.</p> <p>11 Q. Did you know that their website</p> <p>12 lists talc as a cause of ovarian cancer?</p> <p>13 MR. HEGARTY: Objection. Form.</p> <p>14 THE WITNESS: At the medical</p> <p>15 school?</p> <p>16 QUESTIONS BY MR. BOWDEN:</p> <p>17 Q. I'm sorry, as a risk -- did you</p> <p>18 know that University of Vermont --</p> <p>19 A. Yes.</p> <p>20 Q. -- lists talc as a risk factor</p> <p>21 for ovarian cancer?</p> <p>22 MR. DONATH: Objection to form.</p> <p>23 THE WITNESS: You're talking</p> <p>24 about the medical school at the</p> <p>25 University of Vermont, I presume?</p>

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<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. Either one. 3 Are you aware of either one? 4 A. Well, I doubt if the 5 University -- 6 MR. DAVANT: Objection to form. 7 THE WITNESS: -- of Vermont 8 website, which is about education, 9 would list something medical, but 10 maybe they do. But I wasn't aware of 11 that. 12 QUESTIONS BY MR. BOWDEN: 13 Q. Okay. You weren't aware that 14 the medical university listed it as a 15 possible risk of ovarian cancer? 16 A. No, I was not. 17 MR. DAVANT: Same objection. 18 QUESTIONS BY MR. BOWDEN: 19 Q. Is there any risk of cancer, 20 ovarian cancer, that is acceptable in a 21 cosmetic product? 22 MR. DONATH: Objection. Form. 23 MR. BILLINGS-KANG: Objection. 24 Asked and answered. 25 THE WITNESS: No.</p>	<p>1 period. 2 MR. TISI: He said no, period. 3 MR. DAVANT: I'm looking at 4 this right here: "State your answer 5 again." 6 Answer: -- 7 MR. TISI: No, that's the 8 question before. 9 MR. DAVANT: Had you finished 10 your answer -- 11 THE WITNESS: No. 12 MR. DAVANT: -- before you were 13 interrupted? 14 MR. BOWDEN: There's no 15 question pending. 16 THE WITNESS: No, I was going 17 to add to it. 18 MR. DAVANT: All right. Move 19 to strike. 20 QUESTIONS BY MR. BOWDEN: 21 Q. Are you familiar with the 22 precautionary principle? 23 A. Yes. 24 Q. State for us what the 25 precautionary principle is.</p>
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<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. State your answer again. 3 A. Any risk of -- state that 4 again? I'm sorry, could you state that again 5 or read it back? 6 MR. DAVANT: "Is there any risk 7 of cancer, ovarian cancer, that is 8 acceptable in a cosmetic product?" 9 MR. BOWDEN: Hold on. You can 10 ask him during your deposition. 11 MR. DAVANT: He's asked to read 12 your question back. 13 MR. BOWDEN: There's a question 14 and an answer. We're moving on. 15 MR. DAVANT: I don't think his 16 answer matched the question because 17 everybody was objecting at the time. 18 MR. TISI: Actually, she got it 19 down just right, Counsel. 20 MR. DAVANT: No, I don't 21 think -- I don't think he -- he did 22 finish his answer. I'm not trying to 23 be obstructive. Unless I'm looking at 24 the wrong thing. I might be -- 25 MR. BOWDEN: He said no,</p>	<p>1 A. Essentially says if -- in loose 2 words it says that if a substance is a 3 carcinogen or has toxic properties and it's 4 known, it should be avoided -- or it should 5 be controlled to the lowest possible level. 6 Q. It doesn't say "known," doesn't 7 it? 8 A. That's not it. 9 Q. Okay. Let me ask you this: Is 10 there any level of a carcinogen that's 11 acceptable in a consumer product? 12 MR. DONATH: Objection to form. 13 THE WITNESS: There are -- 14 there are some in consumer products, 15 yes. 16 QUESTIONS BY MR. BOWDEN: 17 Q. I'm not asking you whether they 18 exist. I'm asking you whether they're 19 acceptable. 20 MR. DONATH: Objection to form. 21 THE WITNESS: I would have to 22 look at the literature. I would have 23 to do a search. I would suspect there 24 are some. 25</p>

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<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. Should they be warned of? 3 MR. DONATH: Objection to form. 4 MR. BILLINGS-KANG: Objection. 5 THE WITNESS: If the risk rises 6 to a certain level, yes, there should 7 be warning. 8 QUESTIONS BY MR. BOWDEN: 9 Q. And when you're talking about 10 rising to a certain level, that's in 11 comparison to a benefit, true? 12 MR. DONATH: Objection to form. 13 THE WITNESS: Yes. 14 QUESTIONS BY MR. BOWDEN: 15 Q. It's a balancing act, right? 16 A. Yes. 17 Q. And so if you don't know what 18 the threshold risk is and there's no medical 19 or therapeutic benefit to a product, that 20 risk would not be acceptable, true? 21 MR. DONATH: Objection to form. 22 MR. HEGARTY: Objection. Form. 23 THE WITNESS: I haven't really 24 studied that subject closely. 25</p>	<p>1 there's sufficient evidence that 2 there's a relationship with cancer and 3 there's not a threshold, then I would 4 say it should be -- there should be 5 warnings about it. 6 MR. BOWDEN: All right. Take a 7 break? 8 MR. DONATH: Sure. 9 VIDEOGRAPHER: The time is now 10 1:08. Going off the record. 11 (Off the record at 1:08 p.m.) 12 VIDEOGRAPHER: Okay. The time 13 is now 1:58. Back on the record. 14 QUESTIONS BY MR. BOWDEN: 15 Q. All right. When we left off 16 for our break, we were discussing the IARC 17 proceedings and the efforts that were being 18 made leading up to it. 19 A. Yes. 20 Q. And we had discussed briefly 21 the presentation that you had made to some of 22 the industry observers -- 23 A. Yes. 24 Q. -- and now I want to move 25 forward into the actual IARC proceedings</p>
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<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. It's not a subject; it's a 3 question. 4 A. Well, I don't want to answer it 5 without -- you know, top of my head without 6 some knowledge of the subject. 7 Q. I'm asking you as a 8 hypothetical, as a person who is out there 9 giving presentations to industry observers, 10 as a person who is giving scientific opinions 11 to others: What is it -- strike that. 12 If you don't know what the 13 threshold level of a causative agent -- 14 strike that. 15 If you don't know what the 16 threshold level is that raised the risk of 17 causing cancer, there is no amount of that 18 agent that's acceptable in a personal care 19 product? 20 MR. DONATH: Objection to form. 21 MR. BILLINGS-KANG: Objection. 22 Asked and answered. Beyond the scope. 23 THE WITNESS: We have to be 24 careful, certainly, with -- with what 25 are in personal care products. If</p>	<p>1 themselves. 2 Okay? 3 A. Okay. 4 Q. And so we discussed a little 5 bit that -- strike that. 6 We discussed before our break 7 that there's a support team on the ground in 8 Lyon, France, correct? 9 A. Yes. 10 Q. And the IARC proceedings took 11 place over about a week? 12 A. I think it might have stretched 13 into the second week. It may have gone 14 from -- 15 Q. For the voting process. 16 A. -- Monday to Friday, and then 17 Monday and they voted Tuesday, something like 18 that. I can't recall. 19 Q. Right. 20 And so you were there the 21 entire time, right? 22 A. Yes. Yes. 23 Q. Dr. Muscat was there the entire 24 time? 25 A. Yes. Yes.</p>

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<p style="text-align: right;">Page 290</p> <p>1 Q. And part of your role at the 2 IARC proceedings was to coordinate, right, to 3 coordinate what information and feedback was 4 going to and from the industry observers, 5 right?</p> <p>6 MR. BILLINGS-KANG: Objection. 7 Asked and answered. 8 MR. DONATH: Objection. 9 THE WITNESS: Yeah, we would 10 find out from Dr. Muscat what was 11 taking place during the meeting and if 12 there was anything that we could get 13 to augment the information at the 14 meeting.</p> <p>15 QUESTIONS BY MR. BOWDEN: 16 Q. Okay. And so as part of that 17 process, Dr. Muscat would come out in the 18 evenings and he would provide a daily report 19 to the trade organization being -- well, it 20 wasn't a trade organization, it was a group 21 of people that was involved, that list of 22 people we went through earlier, right?</p> <p>23 A. Yes. 24 Q. I'm going to mark for you 25 Exhibit Number 23.</p>	<p style="text-align: right;">Page 292</p> <p>1 the limitations of the Cramer, et al., study. 2 Please direct any insights you may have to 3 the talc industry observers, the Lyon-based 4 team and the trade association points of 5 contact" -- I'll re-read it. 6 "Please direct any insights you 7 may have to the talc industry observers, the 8 Lyon-based team and the trade association 9 points of contact using the following 10 hyperlink." 11 Do you see where that's listed 12 down there? 13 A. Yes. Yes. 14 Q. And there's a couple of names. 15 One is Eric Turner, right? 16 A. In the "from"? 17 Q. In the support team 18 distribution list. 19 A. Oh. 20 Q. These are the people that are 21 running support on the ground, right? 22 A. Yeah. 23 Not all these people are in 24 Lyon. 25 Q. Right. Right. Poor choice of</p>
<p style="text-align: right;">Page 291</p> <p>1 MR. BOWDEN: And Mr. Smith, 2 this will be P1.059. 3 (Glenn Exhibit 23 marked for 4 identification.) 5 QUESTIONS BY MR. BOWDEN: 6 Q. Now, did you review this 7 document in preparation for today? 8 A. I did see this, yes. 9 Q. And you're very familiar with 10 the IARC process, right? 11 A. Somewhat, yes. 12 Q. Okay. I want to start off 13 on -- I'm going to start off on page 5, so 14 that would be 59.5. 15 A. Okay. 16 Q. Do you see this e-mail from 17 Mark Ellis? 18 A. Yes. 19 Q. And he's sending it out to a 20 group of folks, right? 21 A. Yes. 22 Q. And at the bottom it says, "The 23 Lyon-based supported team has determined it 24 is critical that the larger overall support 25 team provides scientific reasoning to address</p>	<p style="text-align: right;">Page 293</p> <p>1 words on my part. 2 But these are the people who 3 were going to be helping disseminate the 4 information from the observers and helping 5 coordinate information going back to the 6 observers, right? 7 MR. HEGARTY: Objection. Form. 8 THE WITNESS: Yes, to 9 Dr. Muscat, yes. 10 QUESTIONS BY MR. BOWDEN: 11 Q. Right. 12 And you're one of the people 13 that's listed there, right? 14 RGlenn@Crowell.com? 15 A. Yes. 16 Q. Now, on February 8th, if you go 17 to 59.6... 18 A. What was the date of this? 19 February? 20 Q. It's just the next page over. 21 A. Yeah. 22 Q. You see there's an e-mail at 23 the bottom from you? 24 A. Yes. 25 Q. And that's February 8th?</p>

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<p>1 A. Yes.</p> <p>2 Q. And you're sending it to the</p> <p>3 same group of people, or some of the same</p> <p>4 members, right?</p> <p>5 A. Yeah.</p> <p>6 Q. And it says, "Privileged and</p> <p>7 confidential, attorney-client communication."</p> <p>8 Was that just a signature page,</p> <p>9 something that automatically appeared on your</p> <p>10 e-mails?</p> <p>11 A. It didn't automatically. I</p> <p>12 think that's how I put it in.</p> <p>13 Q. Who asked you to put it there?</p> <p>14 A. No one.</p> <p>15 Q. You just felt that it would be</p> <p>16 appropriate to do?</p> <p>17 A. I did.</p> <p>18 Q. Okay.</p> <p>19 A. I put it in for some reason I</p> <p>20 don't know.</p> <p>21 Q. Okay. Turn to the next page,</p> <p>22 and you list key points, right?</p> <p>23 A. Yes.</p> <p>24 Q. And these are key points from</p> <p>25 the epidemiology session at which Dr. Muscat</p>	<p>1 more -- a more realistic or</p> <p>2 scientifically reliable introduction</p> <p>3 of talc to the ovary than perineal</p> <p>4 dusting.</p> <p>5 QUESTIONS BY MR. BOWDEN:</p> <p>6 Q. Sure.</p> <p>7 And I'm not -- I'm not trying</p> <p>8 to quibble with you --</p> <p>9 A. Okay.</p> <p>10 Q. -- about what it was he was</p> <p>11 trying to say to them.</p> <p>12 A. Right.</p> <p>13 Q. What I'm asking is whether what</p> <p>14 he was saying, the substance of what he was</p> <p>15 saying, was the same substance or the same</p> <p>16 issue that he was being paid for to write a</p> <p>17 report on behalf of Crowell &amp; Moring --</p> <p>18 A. Yeah.</p> <p>19 Q. -- Johnson &amp; Johnson and</p> <p>20 Luzenac; is that correct?</p> <p>21 MR. DONATH: Objection. Form.</p> <p>22 MR. HEGARTY: Objection. Form.</p> <p>23 QUESTIONS BY MR. BOWDEN:</p> <p>24 Q. Is that correct?</p> <p>25 A. Yes. Yes.</p>
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<p>1 was serving as the industry observer, right?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And if you look halfway</p> <p>4 down that page, there's one that starts</p> <p>5 "Dr. Muscat."</p> <p>6 A. Yes.</p> <p>7 Q. "Dr. Muscat introduced into the</p> <p>8 discussion the fact that talc diaphragm</p> <p>9 studies did not show a relationship with the</p> <p>10 scientific premise that talc-coated</p> <p>11 diaphragms would be a more plausible and</p> <p>12 direct route of exposure than perineal</p> <p>13 dusting."</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. And what he's doing there, he's</p> <p>17 making sure that the working group is aware</p> <p>18 of the -- of the premise -- the hypothesis of</p> <p>19 the paper that he was working for Crowell &amp;</p> <p>20 Moring on, right?</p> <p>21 MR. DONATH: Objection to form.</p> <p>22 MR. HEGARTY: Objection. Form.</p> <p>23 THE WITNESS: In making the</p> <p>24 point that as far as a route of entry,</p> <p>25 the diaphragm would probably be</p>	<p>1 Q. Okay.</p> <p>2 A. Actually --</p> <p>3 Q. And then at the bottom --</p> <p>4 A. -- the talc-diaphragm study was</p> <p>5 more under Dr. Huncharek. Dr. Muscat was</p> <p>6 acting as a --</p> <p>7 Q. Dr. Muscat is listed as one of</p> <p>8 the authors of that paper, right?</p> <p>9 A. Yes. Yes.</p> <p>10 Q. Okay. And that means that he</p> <p>11 had significant input into it, correct?</p> <p>12 MR. HEGARTY: Objection. Form.</p> <p>13 THE WITNESS: Yes.</p> <p>14 QUESTIONS BY MR. BOWDEN:</p> <p>15 Q. At the bottom of that page it</p> <p>16 says, "Dr. Muscat is waiting."</p> <p>17 Do you see the bottom?</p> <p>18 A. Yes.</p> <p>19 Q. And I'm pulling it up here on</p> <p>20 the screen here, too, if that's easier.</p> <p>21 "Dr. Muscat is waiting to</p> <p>22 introduce the use of talc as a sclerosing</p> <p>23 agent in pleurodesis and its lack of</p> <p>24 mesotheliogenic potential on the pleura and</p> <p>25 how that observation relates to a lack of</p>

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<p style="text-align: right;">Page 298</p> <p>1 potential as an ovarian carcinogen." 2 Do you see that? 3 A. Yes. 4 Q. And that was actually the 5 hypothesis that you came up with during that 6 strategy session that we reviewed back in 7 2005, right? 8 MR. DONATH: Objection. Form. 9 THE WITNESS: That's right. 10 QUESTIONS BY MR. BOWDEN: 11 Q. Okay. And that was the idea 12 that you put forth that they ultimately 13 adopted and put into the paper, correct? 14 A. Yes. 15 Q. Okay. And then at the bottom 16 there -- or excuse me, it says, "It is our 17 intention to discuss this with 18 Dr. Oberdörster and Muscat tomorrow evening." 19 Do you see that? 20 A. Wait a minute. Is that on 7? 21 Q. It's on 8. I continued over. 22 Let me strike that question. 23 A. Oh, I'm sorry. 24 Q. That's okay. 25 MR. BOWDEN: So, Corey, let's</p>	<p style="text-align: right;">Page 300</p> <p>1 section. 2 Q. Okay. The work assignment, "It 3 is critical that the support team provide 4 scientific reasoning to knock the 5 underpinnings from the Cramer, et al., 6 studies." 7 Do you see that there? 8 A. Yes. Yes, I do. 9 Q. Now, one of the issues that -- 10 as viewed by the group that was there and the 11 group -- the larger group on this e-mail was 12 that the epidemiology session was giving 13 greater weight to the Cramer studies, right? 14 MR. HEGARTY: Objection. Form. 15 THE WITNESS: They did give 16 considerable weight to the Cramer 17 studies, yes. 18 QUESTIONS BY MR. BOWDEN: 19 Q. Right. And they actually 20 said -- they made the comment that they felt 21 that that was the most robust study on the 22 issue? 23 MR. HEGARTY: Objection. Form. 24 THE WITNESS: I think if they 25 made that comment, it was made about</p>
<p style="text-align: right;">Page 299</p> <p>1 actually bring out the bullet point in 2 front of it as well. 3 QUESTIONS BY MR. BOWDEN: 4 Q. And now we're talking about the 5 pleurodesis information, correct? 6 A. Correct. Yes. 7 Q. It says, "It is likely that 8 this issue would be introduced at the plenary 9 session where it could receive support from 10 Drs. Oberdörster and Antony," right? 11 A. Yes. 12 MR. DONATH: Objection to form. 13 QUESTIONS BY MR. BOWDEN: 14 Q. And Antony, that's the 15 Dr. Antony you were referring to earlier? 16 A. It's Dr. Vena Antony, yes. 17 Q. Okay. And then the next bullet 18 point is, "It is our intention to discuss 19 this with Dr. Oberdörster and Muscat tomorrow 20 evening," right? 21 A. Correct. 22 Q. And the work assignment -- 23 A. Let me just add, the reason to 24 bring it out in the plenary session is that 25 Dr. Antony was not in the epidemiology</p>	<p style="text-align: right;">Page 301</p> <p>1 the Gertig study, who was -- who 2 Dr. Cramer was a coauthor on. 3 QUESTIONS BY MR. BOWDEN: 4 Q. Right. 5 A. Dr. Gertig. 6 Q. That was Dr. Hankinson as well, 7 right? 8 A. Yes. I think Dr. Gertig was 9 from Australia. She evidently was doing a 10 fellowship or something there. 11 Q. Fair to say, though, that they 12 gave that study greater weight, correct? 13 A. If it was the Gertig study, 14 yes, they should have. 15 Q. So I want to go 59.2 now. 16 A. Okay. 17 Q. And at the top it says, "Bob, 18 please forward this e-mail to the list. I 19 will be back at the Hilton at about ten 20 o'clock." 21 A. Yeah. 22 Q. And that's from Dr. Muscat, 23 right? 24 A. Yes. 25 Q. And that was his -- this is</p>

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<p>1 actually -- if you flip to the front page at</p> <p>2 the bottom, it shows this is the daily report</p> <p>3 from February 8, 2006, right?</p> <p>4 A. Right.</p> <p>5 And when was that last one that</p> <p>6 I wrote? February 8th also.</p> <p>7 Q. Right.</p> <p>8 A. Okay.</p> <p>9 Q. A lot of communication going</p> <p>10 back and forth on these days, right?</p> <p>11 A. Yeah. Right. And to the group</p> <p>12 outside as well.</p> <p>13 Q. Sure. Sure.</p> <p>14 Anyway, on the second page, if</p> <p>15 you look down at the second paragraph where</p> <p>16 it says "I introduced"?</p> <p>17 A. Yes.</p> <p>18 Q. This is Dr. Huncharek -- or</p> <p>19 excuse me, Dr. Muscat giving a report to you</p> <p>20 to forward on to the group about what he did,</p> <p>21 right?</p> <p>22 A. Yes.</p> <p>23 Q. And he says, "I introduced the</p> <p>24 pleurodesis data and reasoning. The group</p> <p>25 agreed to take this into consideration."</p>	<p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. Down there it says, in the</p> <p>4 middle of that paragraph, "Dr. Demers stated</p> <p>5 that diaphragms are often coated with a</p> <p>6 spermicide jelly and that this may prevent</p> <p>7 the release of particles."</p> <p>8 Right?</p> <p>9 Do you see where that's</p> <p>10 written?</p> <p>11 A. Yes.</p> <p>12 Q. "This is a valid point."</p> <p>13 Do you see where that's</p> <p>14 written?</p> <p>15 A. Yes.</p> <p>16 Q. That's Dr. Muscat's words,</p> <p>17 correct?</p> <p>18 A. Yes.</p> <p>19 Q. Now, Dr. Muscat ultimately</p> <p>20 published the diaphragm study along with</p> <p>21 Dr. Huncharek, correct?</p> <p>22 A. Correct.</p> <p>23 Q. And that valid point that he</p> <p>24 took away from the IARC work group, you know</p> <p>25 that that does not appear anywhere in the</p>
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<p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. And if you go down to -- if you</p> <p>4 continue reading, it says, "Dr. Demers was</p> <p>5 charged with writing a summary of this data</p> <p>6 for the volume. I am unsure that this will</p> <p>7 be persuasive in the next vote. Dr. Demers</p> <p>8 indicated to me that he thought this</p> <p>9 information was anecdotal because it is</p> <p>10 limited in scope compared to the ovarian</p> <p>11 studies and that the information consisted of</p> <p>12 case series."</p> <p>13 Do you see that?</p> <p>14 A. I do.</p> <p>15 Q. And I'm not asking you whether</p> <p>16 you agree with it; I'm just asking if that's</p> <p>17 what the report was back from the group.</p> <p>18 Correct?</p> <p>19 A. It was, but it's --</p> <p>20 Q. Okay.</p> <p>21 A. -- kind of odd that Dr. Demers</p> <p>22 had already formed his opinion when he just</p> <p>23 heard of the subject.</p> <p>24 Q. So if we continue on down, it</p> <p>25 says, "Dr. Hankinson was cautious."</p>	<p>1 diaphragm study, correct?</p> <p>2 MR. HEGARTY: Objection.</p> <p>3 Correct.</p> <p>4 THE WITNESS: I don't know</p> <p>5 whether Dr. Demers was a gynecologist</p> <p>6 and whether he was familiar with</p> <p>7 spermicidal jellies being used either.</p> <p>8 And it says "often used"; it doesn't</p> <p>9 say "always used."</p> <p>10 QUESTIONS BY MR. BOWDEN:</p> <p>11 Q. My question to you is, when the</p> <p>12 diaphragm study was ultimately published, was</p> <p>13 that point mentioned in there?</p> <p>14 A. I don't recall it being</p> <p>15 mentioned. I don't recall it being</p> <p>16 mentioned.</p> <p>17 Q. Okay. Let's continue on. Two</p> <p>18 more paragraphs down, "Dr. Hankinson</p> <p>19 indicated"?</p> <p>20 A. Yes.</p> <p>21 Q. "Dr. Hankinson indicated that</p> <p>22 she did not believe confounding was an</p> <p>23 issue."</p> <p>24 And she's talking about the epi</p> <p>25 studies; is that right?</p>

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<p>1 A. She's probably talking about</p> <p>2 her own work with Dr. Cramer.</p> <p>3 Q. "She noted little change</p> <p>4 between age-adjusted risk estimates and</p> <p>5 models that incorporated other variables.</p> <p>6 She stated that since known confounders did</p> <p>7 not change the estimates, she could not make</p> <p>8 the assumption that there were other unknown</p> <p>9 potential factors that could be confounders."</p> <p>10 Do you see where that's</p> <p>11 written?</p> <p>12 A. "She made the assumption there</p> <p>13 were other..." There were other on the -- on</p> <p>14 the potential confounders, yes, there were.</p> <p>15 Q. Did I read that correctly?</p> <p>16 A. Yes.</p> <p>17 Q. "Michael Huncharek pointed out</p> <p>18 that none of these studies controlled for</p> <p>19 smoking, and new data indicate that smoking</p> <p>20 is related to ovarian cancer."</p> <p>21 Do you see where that's</p> <p>22 written?</p> <p>23 A. Yes, and many of them --</p> <p>24 Q. And this is February of 2006?</p> <p>25 A. Many of them didn't control for</p>	<p>1 QUESTIONS BY MR. BOWDEN:</p> <p>2 Q. Let me ask you before we play</p> <p>3 this: Are you familiar with Dr. Nicholson?</p> <p>4 A. Of Mount Sinai?</p> <p>5 Q. No, sir, of Johnson &amp; Johnson.</p> <p>6 A. I thought you meant the</p> <p>7 asbestos researcher.</p> <p>8 No, I do not know a</p> <p>9 Dr. Nicholson.</p> <p>10 Q. Do you know that we took her</p> <p>11 deposition in this case and that she speaks</p> <p>12 for J&amp;J?</p> <p>13 MR. HEGARTY: Objection. Form.</p> <p>14 MR. DONATH: Objection. Form.</p> <p>15 THE WITNESS: I did not know</p> <p>16 that.</p> <p>17 MR. BOWDEN: Okay. I want you</p> <p>18 to watch this clip from her</p> <p>19 deposition, please.</p> <p>20 (Video played.)</p> <p>21 QUESTIONS BY MR. BOWDEN:</p> <p>22 Q. Go back to 59.2, please.</p> <p>23 "Dr. Muscat, as the IARC</p> <p>24 industry observer, on behalf of" --</p> <p>25 A. Where are you now?</p>
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<p>1 BRCA1 or BRCA2 gene deficiencies. They</p> <p>2 didn't control --</p> <p>3 Q. Sir, my question is</p> <p>4 specifically about what's written here.</p> <p>5 A. They did not control --</p> <p>6 Q. They didn't control smoking --</p> <p>7 A. -- for the most common causes</p> <p>8 of ovarian cancer.</p> <p>9 Q. Dr. Huncharek pointed out -- he</p> <p>10 was not there on the ground, right?</p> <p>11 A. That's right.</p> <p>12 Q. Dr. Huncharek pointed out that</p> <p>13 none of these studies controlled for smoking,</p> <p>14 right?</p> <p>15 A. Yes.</p> <p>16 Q. The very next sentence from</p> <p>17 Dr. Muscat is, "I brought this up in</p> <p>18 session."</p> <p>19 Have I read that correctly?</p> <p>20 A. Let me find it again.</p> <p>21 Q. It's on the screen in front of</p> <p>22 you, sir.</p> <p>23 A. Oh, okay. Yes. Yes.</p> <p>24 MR. BOWDEN: Can we play the</p> <p>25 clip from Dr. Nicholson, please?</p>	<p>1 Q. I'm sorry, do you -- let me</p> <p>2 just back up and strike that.</p> <p>3 Do you agree with what you just</p> <p>4 saw from Dr. Nicholson?</p> <p>5 A. I have not read the literature</p> <p>6 related to smoking and ovarian cancer, so I</p> <p>7 wouldn't agree with either one of them.</p> <p>8 Q. You don't know one way or an</p> <p>9 other?</p> <p>10 A. I don't know one way or the</p> <p>11 other.</p> <p>12 Q. But that's exactly what message</p> <p>13 was being brought up at the IARC proceedings</p> <p>14 by Dr. Muscat, correct?</p> <p>15 A. I don't know whether Dr. Muscat</p> <p>16 had information of that or not.</p> <p>17 Q. Let's go back and read this.</p> <p>18 A. He -- I thought it was --</p> <p>19 Q. "Dr. Huncharek pointed out that</p> <p>20 none of these studies controlled for smoking,</p> <p>21 and new data indicate that smoking is related</p> <p>22 to ovarian cancer."</p> <p>23 You see where that's written?</p> <p>24 A. Yes, I've not read --</p> <p>25 Q. "I brought this up in session."</p>



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<p>1 The "I" in that sentence is Dr. Muscat, 2 correct? 3 A. Muscat, right. Right. 4 Q. Dr. Muscat, the industry 5 observer, brought that up to the IARC -- 6 A. That Dr. Huncharek considered 7 to be new studies of confounding from smoking 8 with ovarian cancer, yes. 9 I have not read that -- that 10 work, so I can't comment whether the good 11 doctor on the screen was right or whether 12 Dr. Huncharek was right. 13 Q. Well, you're aware that the 14 original paper -- oh, yeah. 15 Are you aware that Dr. Muscat 16 has testified that he didn't believe that 17 either? 18 MR. HEGARTY: Objection to 19 form. 20 MR. DONATH: Objection to form. 21 THE WITNESS: No, I have not 22 read that. 23 QUESTIONS BY MR. BOWDEN: 24 Q. Okay. In fact, you know that 25 the Critical Review paper, which we took a</p>	<p>1 literature myself. If the reviewers 2 would determine that there was not 3 support, scientific support, for it, 4 no, it wouldn't surprise me that they 5 suggested taking it out. 6 QUESTIONS BY MR. BOWDEN: 7 Q. And it doesn't exist in the 8 paper as published, true? 9 MR. HEGARTY: Objection. Form. 10 THE WITNESS: I'd have to read 11 the paper, which I'm taking at your 12 word. 13 QUESTIONS BY MR. BOWDEN: 14 Q. Okay. All right. So I said 15 the review -- well, strike that. 16 Let me go to P1.0073. I'm 17 going to mark this for you as Exhibit 18 Number 24. 19 I'm sorry, this is -- you can 20 take that back. That's the same. It's just 21 a different number. 22 A. Yeah, I thought -- 23 Q. Yeah, it's a different Bates 24 production of the... 25 MR. BOWDEN: Are you okay with</p>
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<p>1 look at a little bit earlier, that originally 2 when they submitted to the Europe Journal of 3 Cancer Prevention, they had a statement in 4 there about smoking as a confounder, right? 5 MR. HEGARTY: Objection. Form. 6 THE WITNESS: I did not know 7 that. 8 QUESTIONS BY MR. BOWDEN: 9 Q. You did not know that? 10 A. I don't recall reading that 11 manuscript that carefully. 12 Q. Okay. Would it surprise you if 13 Dr. Huncharek had put it in there? 14 MR. HEGARTY: Objection. Form. 15 MR. DONATH: Objection. Form. 16 THE WITNESS: If that was his 17 opinion and he had a basis for it, it 18 wouldn't surprise me. 19 QUESTIONS BY MR. BOWDEN: 20 Q. Would it surprise you that the 21 reviewers said that there's no support for 22 this and you should take it out? 23 MR. HEGARTY: Objection. Form. 24 THE WITNESS: Again, I just 25 told you, I have not read the</p>	<p>1 that, Counsel, if I take that and just 2 put it on the next one? 3 (Glenn Exhibit 24 marked for 4 identification.) 5 QUESTIONS BY MR. BOWDEN: 6 Q. All right. Go to P1.65 next. 7 All right. We'll make this one 8 number 24 for you. 9 So now we've gone a couple days 10 forward here. You see this is an e-mail from 11 Michele Wyart on February 11th. 12 Do you see that down in the 13 middle of the first paragraph -- the first 14 page? 15 A. It's to Michele Wyart. 16 MR. BOWDEN: Yeah. Can you 17 pull up this original message here in 18 the middle? 19 QUESTIONS BY MR. BOWDEN: 20 Q. Mr. Glenn, I'm looking at the 21 middle of the page. I think you might be 22 looking at the top of it. 23 A. Oh. 24 Q. So I pulled it up on the screen 25 here for you.</p>

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<p>1 A. Okay.</p> <p>2 Q. All right.</p> <p>3 A. Yeah.</p> <p>4 Q. So this is the message from</p> <p>5 Michele, IMA-Europe --</p> <p>6 A. Yes.</p> <p>7 Q. -- on February 11th.</p> <p>8 Are you with me now?</p> <p>9 A. Right. Yes.</p> <p>10 Q. Okay.</p> <p>11 And this is talking to you,</p> <p>12 Eric and John; again, some of the contact</p> <p>13 people, Eric Turner, yourself, John Muscat?</p> <p>14 A. Actually, John is John Parks.</p> <p>15 Q. I'm sorry, that's right. And</p> <p>16 he's with Minerals Tech, right?</p> <p>17 A. Yes.</p> <p>18 Q. All right. And she's thanking</p> <p>19 you for the reports, and she's offering some</p> <p>20 comments, right?</p> <p>21 A. Yes.</p> <p>22 Q. And what she's asking in this</p> <p>23 case is at this point was there concern that</p> <p>24 the IARC work group was going to recommend</p> <p>25 that talc be listed as a possible carcinogen?</p>	<p>1 evidence for industrial talc?"</p> <p>2 Right?</p> <p>3 A. Yes.</p> <p>4 Q. And "Cosmetic talc is one of</p> <p>5 the purest talc product. The regulatory</p> <p>6 bodies will have difficulties to digest and</p> <p>7 evaluate. There is a risk that they</p> <p>8 understand, and the market and public, too,</p> <p>9 that the evidence is there, but the studies</p> <p>10 in the industrial settings were not of</p> <p>11 sufficient quality."</p> <p>12 Do you see that there?</p> <p>13 A. Yes. I do. I do.</p> <p>14 Q. Do you agree with that</p> <p>15 statement?</p> <p>16 A. Pardon?</p> <p>17 Q. Do you agree with that</p> <p>18 statement?</p> <p>19 "There is a risk that they</p> <p>20 understand" --</p> <p>21 A. Yeah.</p> <p>22 Q. -- "they" being the regulatory</p> <p>23 bodies -- and she puts in parentheses, "and</p> <p>24 the market and public, too."</p> <p>25 A. Yeah.</p>
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<p>1 MR. DONATH: Objection. Form.</p> <p>2 THE WITNESS: I'm not sure.</p> <p>3 QUESTIONS BY MR. BOWDEN:</p> <p>4 Q. Okay.</p> <p>5 A. I don't recall that.</p> <p>6 Q. All right. Well, let's read</p> <p>7 through this. "Thank you for the report,</p> <p>8 although late in the night so complete and</p> <p>9 structured. The market-base people should</p> <p>10 rapidly give an opinion on a possible</p> <p>11 separate and more stringent evaluation of</p> <p>12 cosmetic talc. The first remarks which come</p> <p>13 to me are the following: Although cosmetic</p> <p>14 application is limited to 4 percent of the</p> <p>15 market, cosmetic talc is a leading product</p> <p>16 for industry which grade is also used in a</p> <p>17 series of applications with human contact and</p> <p>18 large added value. If cosmetic talc is</p> <p>19 classified, why not food grade talc and</p> <p>20 pharmaceutical talc."</p> <p>21 Do you see that there?</p> <p>22 A. Yes.</p> <p>23 Q. It continues on to the next</p> <p>24 page: "What does it mean to conclude limited</p> <p>25 evidence for cosmetic talc and insufficient</p>	<p>1 Q. The public are the consumers,</p> <p>2 right?</p> <p>3 A. Right.</p> <p>4 Q. -- "that the evidence is there,</p> <p>5 but the studies in the industrial settings</p> <p>6 were not of sufficient quality."</p> <p>7 MR. DONATH: Objection. Form.</p> <p>8 THE WITNESS: I'm not sure what</p> <p>9 Michele is really meaning there,</p> <p>10 especially when she says the studies</p> <p>11 in the industrial settings were not of</p> <p>12 sufficient quality. The suggestions</p> <p>13 of talc workers were pretty clearly --</p> <p>14 QUESTIONS BY MR. BOWDEN:</p> <p>15 Q. But the cosmetic talc did come</p> <p>16 out with a 2B rating, right?</p> <p>17 A. It did, 2B, possible, yeah.</p> <p>18 MR. DONATH: Objection. Form.</p> <p>19 QUESTIONS BY MR. BOWDEN:</p> <p>20 Q. At the bottom of that she says,</p> <p>21 "Sorry to mix science and market, but that is</p> <p>22 the reality of the Lyon outcome," right?</p> <p>23 MR. HEGARTY: Objection. Form.</p> <p>24 THE WITNESS: That was her</p> <p>25 opinion. It was never mine.</p>

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<p style="text-align: right;">Page 318</p> <p>1 QUESTIONS BY MR. BOWDEN: 2 Q. Well, you know that if the IARC 3 proceedings were to consider talc, cosmetic 4 talc, to be a possible carcinogen, that that 5 could have an impact on the market, right? 6 MR. HEGARTY: Objection. Form. 7 MR. DONATH: Objection. Form. 8 THE WITNESS: I suppose it 9 could, but that was not of my interest 10 at all, and those things had never 11 been. 12 When silica was considered a 13 carcinogen, the chairman of my 14 association said, "We need to know the 15 truth so that we can do the right 16 thing for our employees and our 17 customers," and that was one of the 18 great public health lessons I got, and 19 it came from a CEO. 20 MR. BOWDEN: I move to strike. 21 Nonresponsive. 22 THE WITNESS: Good. I would 23 never -- 24 MR. BOWDEN: There's no 25 question pending, sir.</p>	<p style="text-align: right;">Page 320</p> <p>1 talc company we represented, yes. 2 QUESTIONS BY MR. BOWDEN: 3 Q. Don't you feel that as a -- 4 well, strike that. 5 They have a responsibility to 6 act in the public interests, right? 7 MR. DONATH: Objection. Form. 8 THE WITNESS: Are you talking 9 about -- 10 QUESTIONS BY MR. BOWDEN: 11 Q. Oh, I'm sorry. I meant to say 12 the -- Crowell &amp; Moring's -- Luzenac's 13 message, that's Crowell &amp; Moring's 14 responsibility to get that out, correct? 15 MR. DONATH: Objection. Form. 16 MR. DAVANT: Objection. Form. 17 MR. DONATH: Beyond the scope. 18 THE WITNESS: Luzenac's message 19 is Crowell's responsibility? 20 MR. BOWDEN: I'll strike that. 21 THE WITNESS: Never. 22 QUESTIONS BY MR. BOWDEN: 23 Q. Crowell &amp; Moring's client at 24 that time was Luzenac, right? 25 A. Correct. Luzenac America.</p>
<p style="text-align: right;">Page 319</p> <p>1 I'm going to go to P1.056. 2 (Glenn Exhibit 25 marked for 3 identification.) 4 QUESTIONS BY MR. BOWDEN: 5 Q. I'm going to mark this as 6 Exhibit Number 25. 7 Now, Tuesday, February 14th, 8 that's the date of the final vote, right? 9 A. It may have been. 10 Q. Okay. And perineal talc, what 11 the final vote is, was unanimous Group 2B, 12 right? 13 A. Yes. 14 MR. HEGARTY: Objection. Form. 15 QUESTIONS BY MR. BOWDEN: 16 Q. And throughout this time 17 period, as to this time period, the IARC 18 working group proceedings, your employer was 19 the Crowell &amp; Moring law firm, right? 20 A. Correct. 21 Q. And the only corporation they 22 represented at that point, the talc 23 manufacturer, was Luzenac, right? 24 MR. DONATH: Objection. Form. 25 THE WITNESS: That was the only</p>	<p style="text-align: right;">Page 321</p> <p>1 Q. And they were ethically bound 2 to act in their client's best interests, 3 correct? 4 MR. BILLINGS-KANG: Objection. 5 Form. 6 MR. DONATH: Objection to form. 7 MR. DAVANT: Objection. Form. 8 THE WITNESS: Crowell &amp; 9 Moring -- 10 QUESTIONS BY MR. BOWDEN: 11 Q. Crowell &amp; Moring was ethically 12 bound to act in Imerys, Luzenac's, best 13 interest, correct? 14 MR. DONATH: Same objection. 15 THE WITNESS: Not necessarily, 16 I don't think. 17 QUESTIONS BY MR. BOWDEN: 18 Q. Well, they weren't bound to act 19 on behalf of the public, right? 20 A. I'm not an attorney. I think 21 you need to direct that question to an 22 attorney. 23 Q. I understand. 24 But you're working for 25 Crowell &amp; Moring at the time, and you're the</p>

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<p>1 only employee of Crowell &amp; Moring at the IARC 2 proceedings, right? 3 A. Yes, uh-huh. 4 Q. And you're one of the 5 designated points of contact for feeding 6 information into the industry observers and 7 taking reports out, right? 8 MR. DONATH: Objection. Form. 9 MR. BILLINGS-KANG: Objection 10 to form. 11 THE WITNESS: We were -- we 12 were giving information to the 13 observer, yes. 14 QUESTIONS BY MR. BOWDEN: 15 Q. Right. 16 And we've seen now through 17 these documents where specifically your 18 strategies, including pleurodesis, those were 19 offered specifically at the working group 20 proceedings, right? 21 A. They were. 22 Q. And that was strategies that 23 were developed during the course of 24 employment with Crowell &amp; Moring, your course 25 of employment with Crowell &amp; Moring, right?</p>	<p>1 form. 2 MR. DONATH: Objection to form. 3 THE WITNESS: I don't think 4 we're under attack. I didn't see any 5 publications about the trade group or 6 talc itself being a problem. 7 QUESTIONS BY MR. BOWDEN: 8 Q. Okay. 9 A. In fact, I'm not sure that 10 anything came out of the IARC meeting related 11 to publicity about talc being a carcinogen. 12 Q. A rating of 2B came out of it, 13 right? 14 A. Yes, and it was published in 15 Lancet Oncology. 16 Q. Right. 17 A. But I didn't read about it in 18 the New York Times. 19 Q. Okay. Let's move on. Let's 20 put that document aside. 21 Next document is going to be 22 P1.4. 23 VIDEOGRAPHER: The time is now 24 2:30. Going off the record. 25 (Off the record at 2:30 p.m.)</p>
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<p>1 A. Yes. Yes. 2 Q. And that was on behalf of 3 Luzenac, correct? 4 MR. DONATH: Objection to form. 5 THE WITNESS: Yes, Luzenac was 6 a client. 7 QUESTIONS BY MR. BOWDEN: 8 Q. Uh-huh. And that strategy was 9 on their behalf, true? 10 MR. DONATH: Objection. Form. 11 THE WITNESS: It was on their 12 behalf, out of my brain. 13 QUESTIONS BY MR. BOWDEN: 14 Q. And that strategy was in the 15 defense of talc, correct? 16 MR. DONATH: Objection to form. 17 THE WITNESS: That strategy was 18 trying to explain what is the real 19 scientific understanding of talc and 20 ovarian cancer. 21 QUESTIONS BY MR. BOWDEN: 22 Q. And so -- but the talc 23 industry, in the trade group's view, was 24 under attack, right? 25 MR. HEGARTY: Objection to</p>	<p>1 VIDEOGRAPHER: Okay. The time 2 is now 2:31. Back on the record. 3 (Glenn Exhibit 26 marked for 4 identification.) 5 QUESTIONS BY MR. BOWDEN: 6 Q. Mr. Glenn, I'm going to hand 7 you what's marked as Exhibit 26. 8 A. Okay. 9 Q. Did you read this in 10 preparation of today's deposition? 11 A. I don't recall that I did. I 12 don't recall seeing this one. 13 Q. And you see here that this is a 14 letter written from Luzenac, right? 15 A. Yes. 16 Q. And February 25, 2006, they 17 were still a client of Crowell &amp; Moring, 18 right? 19 A. Yes. 20 Q. Okay. And they're writing to 21 Dr. Baan? 22 A. Yes. 23 Q. And Dr. Baan is an officer at 24 IARC, right? 25 A. Yes.</p>

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<p style="text-align: right;">Page 326</p> <p>1 Q. And he was one of the people 2 who received comments on monograph 93, right? 3 A. Yes. 4 Q. Okay. And it says here from 5 Luzenac, "Dear Dr. Baan, we wish to express 6 our disappointment with the recent IARC 7 monograph evaluation process that was used to 8 review non-asbestiform talc and ovarian 9 cancer evidence in -- in addition to the lung 10 cancer evidence." 11 Do you see where that's 12 written? 13 A. Yes. 14 Q. The third paragraph down says, 15 "First, the working group did not contain the 16 necessary expertise to properly evaluate the 17 evidence regarding ovarian cancer." 18 Do you agree with that 19 statement? 20 A. I would have to look back at 21 the members working group, but I think there 22 may -- they may could have had better working 23 group members on that -- on that group. 24 Q. Well, you had mentioned earlier 25 that you felt that they didn't have high</p>	<p style="text-align: right;">Page 328</p> <p>1 this, and I'm not asking you to take 2 authorship of it. 3 A. Yeah. 4 Q. What I'm asking you is whether 5 you agree that the IARC working group did not 6 contain the necessary expertise to properly 7 evaluate the evidence regarding ovarian 8 cancer. 9 A. I want to be kind, but, yes. 10 Q. Okay. The next paragraph down 11 says, "Evaluation of the ovarian cancer human 12 evidence in this case required expertise in a 13 number of areas of gynecologic oncology that 14 should have been addressed by other 15 subgroups, parentheses, exposure and 16 mechanism, and that the single working group 17 member familiar with the ovarian cancer human 18 studies did not have such expertise." 19 Do you see where that's 20 written? 21 A. I don't know who he's referring 22 to as the single group member, but, yes, I 23 see it. I read -- you read that correctly. 24 Q. And so we're going to go down 25 to the final paragraph here. Halfway through</p>
<p style="text-align: right;">Page 327</p> <p>1 turnover, right? 2 A. They -- you often see the same 3 people back on the working group -- 4 Q. And one of the -- 5 A. -- Straif being one. 6 Q. One of the criticisms that your 7 client had at the time, Luzenac, and they're 8 writing to IARC, is that "the working group 9 did not contain the necessary expertise to 10 properly evaluate the evidence." 11 A. That's what he said. 12 Q. Do you agree with that 13 statement? 14 A. I would have had probably some 15 other scientists on the group. 16 Q. I don't understand your 17 response. 18 Do you agree with that 19 statement; yes or no? 20 A. I would have composed a 21 different group, possibly. Some of the 22 people would have been on, some not. 23 I did not write this. It's not 24 my opinion. 25 Q. I understand you did not write</p>	<p style="text-align: right;">Page 329</p> <p>1 it says, "In addition." 2 A. Yes. 3 Q. Okay. "In addition, the 4 preamble states that consideration in 5 selecting working group members is also given 6 to balance of scientific findings and views. 7 In this evaluation, there could be no such 8 balance because 15 of the 16 working group 9 members had no expertise in gynecologic 10 oncology or the ovarian cancer literature." 11 Do you see where that's 12 written? 13 A. Yes. 14 Q. Now, gynecologic oncology -- in 15 fact, she mentioned that now twice in this 16 letter by my count. All right? 17 Do you agree that a 18 gynecological oncologist -- or, excuse me, a 19 gynecologic oncologist is best suited to 20 evaluate and opine on the studies looking at 21 talc and ovarian cancer? 22 MR. DONATH: Objection to form. 23 MR. HEGARTY: Objection to 24 form. 25 THE WITNESS: I think a</p>

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<p style="text-align: right;">Page 330</p> <p>1 gynecologist -- a gynecological 2 oncologist would have been a welcomed 3 addition to the group, yes. 4 QUESTIONS BY MR. BOWDEN: 5 Q. In the preparation and 6 publishing of the two papers we've talked 7 about today, the critical review and the 8 diaphragm study -- 9 A. Yes. 10 Q. -- did you, Crowell &amp; Moring, 11 Johnson &amp; Johnson or Luzenac ever consult 12 with an expert on gynecologic oncology? 13 A. No. 14 MR. DONATH: Objection to form. 15 MR. HEGARTY: Objection. Form. 16 THE WITNESS: We were -- 17 QUESTIONS BY MR. BOWDEN: 18 Q. So my second question to 19 that -- 20 A. We were not -- 21 Q. I'm sorry? 22 A. We were not broadly looking at 23 the entire field. 24 Q. Uh-huh. 25 A. The reason the gynecological</p>	<p style="text-align: right;">Page 332</p> <p>1 When you were working with 2 Johnson &amp; Johnson -- 3 A. Yeah, we did not -- 4 Q. -- Luzenac and MRG Group 5 together -- 6 A. Yeah. 7 Q. -- collectively -- 8 A. Yes. 9 Q. -- and producing, funding, 10 editing and ultimately publishing those 11 papers, did that group working together ever 12 consult with an ovarian cancer expert? 13 MR. HEGARTY: Objection. Form. 14 THE WITNESS: No, we did not. 15 And those papers weren't strongly 16 related to ovarian cancer, other than 17 the epidemiology of ovarian cancer. 18 QUESTIONS BY MR. BOWDEN: 19 Q. To your knowledge, did they 20 ever consult with a gynecologic oncologist or 21 an ovarian cancer expert? 22 MR. DONATH: Objection. Form. 23 MR. HEGARTY: Objection. Form. 24 THE WITNESS: No. 25</p>
<p style="text-align: right;">Page 331</p> <p>1 oncologist would be useful is because of the 2 nature of ovarian cancer and the clinical 3 aspects of ovarian cancer and what are real 4 risk factors for ovarian cancer. 5 MR. BOWDEN: I'm going to move 6 to strike as not responsive. 7 THE WITNESS: Okay. 8 QUESTIONS BY MR. BOWDEN: 9 Q. In your experience with 10 Crowell &amp; Moring, Johnson &amp; Johnson, Luzenac, 11 Meta-Analysis Research Group, in the drafting 12 and publication of the Critical Review and 13 diaphragm study, did they ever consult with 14 an expert on ovarian cancer? 15 MR. DONATH: Wait. I'm going 16 to direct the witness not to answer 17 simply with respect to communications 18 with respect to Luzenac, Imerys and 19 Crowell &amp; Moring. 20 MR. HEGARTY: Objection. 21 QUESTIONS BY MR. BOWDEN: 22 Q. Go ahead and answer. 23 A. Read the -- give me the 24 question again. 25 Q. Sure.</p>	<p style="text-align: right;">Page 333</p> <p>1 QUESTIONS BY MR. BOWDEN: 2 Q. And you didn't bring one over 3 to IARC either, correct? 4 A. No, we did not. 5 Q. I want you to turn to the 6 second page of exhibit -- well, this is 7 Exhibit 26. It's P1.54.2. 8 A. First paragraph? 9 Q. No, sir, I'm going to actually 10 be going to the third paragraph. 11 A. Oh, I thought that was the one 12 you wanted to direct me to. 13 Q. I'm sorry, it'll be the last 14 paragraph. 15 A. Okay. 16 Q. "Due to the above deficiencies 17 and irregularities, we believe IARC should 18 consider carefully whether it should proceed 19 with the publication of the ovarian cancer 20 portion of the evaluation for non-asbestiform 21 talc. We believe it should not, and we 22 formally object to the conduct of the 23 evaluation in a manner that was not 24 consistent with IARC's reputation and its 25 policies and procedures."</p>

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<p style="text-align: right;">Page 334</p> <p>1 Do you see that?</p> <p>2 A. Yes, I do.</p> <p>3 Q. To this day, has IARC changed</p> <p>4 its position as regards non-asbestiform talc?</p> <p>5 A. They haven't bothered to</p> <p>6 consider talc again, so, no, it -- this is</p> <p>7 still their position.</p> <p>8 Q. And now I wanted to ask you --</p> <p>9 A. I do find the first paragraph</p> <p>10 to be very interesting.</p> <p>11 Q. I'm going to ask you a separate</p> <p>12 question right now. You can set that aside.</p> <p>13 We have -- during the IARC</p> <p>14 proceedings, you actually had runners go over</p> <p>15 to Dr. Muscat and bring him newspaper</p> <p>16 articles from the 1970s.</p> <p>17 Do you recall doing that?</p> <p>18 MR. DONATH: Objection to form.</p> <p>19 THE WITNESS: I don't recall</p> <p>20 doing that.</p> <p>21 QUESTIONS BY MR. BOWDEN:</p> <p>22 Q. You also informed him that</p> <p>23 talc, after 1975, did not contain asbestos.</p> <p>24 A. That was the position from the</p> <p>25 Cosmetic Toiletry Fragrances Association,</p>	<p style="text-align: right;">Page 336</p> <p>1 QUESTIONS BY MR. BOWDEN:</p> <p>2 Q. Right.</p> <p>3 And I'm not going to parse</p> <p>4 words with you here on this, and when I'm</p> <p>5 talking about asbestos, I'm talking about a</p> <p>6 single fiber of asbestos in talc, in any</p> <p>7 talcum product that's being used for -- in</p> <p>8 baby talc, for example.</p> <p>9 MR. DONATH: Objection to form.</p> <p>10 THE WITNESS: I can't speak</p> <p>11 broadly about that.</p> <p>12 QUESTIONS BY MR. BOWDEN:</p> <p>13 Q. Why not?</p> <p>14 A. Because it's much more complex</p> <p>15 than that.</p> <p>16 To be -- as OSHA decided in</p> <p>17 their regulation, to be considered an</p> <p>18 asbestos mineral that would cause disease, it</p> <p>19 had to be in an asbestiform habit. And they</p> <p>20 also decided that the asbestiform habit and</p> <p>21 the non-asbestiform habit were easily</p> <p>22 distinguishable and that the non-asbestiform</p> <p>23 habit had little consequence. They could --</p> <p>24 they'd regulate it as a particulate not</p> <p>25 otherwise regulated with a TOV of</p>
<p style="text-align: right;">Page 335</p> <p>1 yes.</p> <p>2 Q. Was that your position?</p> <p>3 A. They set up a standard. I'm</p> <p>4 not -- I never tested talc prior to that, and</p> <p>5 I did read a lot of tests related to talc</p> <p>6 before that.</p> <p>7 Q. So you didn't test the accuracy</p> <p>8 of that statement before relaying it to</p> <p>9 Dr. Muscat?</p> <p>10 A. This was a group effort.</p> <p>11 Q. My question is: You did not --</p> <p>12 A. I did not.</p> <p>13 Q. Crowell &amp; Moring did not?</p> <p>14 A. No.</p> <p>15 Q. And the question of whether</p> <p>16 talc contains asbestos, that's an important</p> <p>17 question, right?</p> <p>18 MR. HEGARTY: Objection to</p> <p>19 form.</p> <p>20 MR. DONATH: Objection. Form.</p> <p>21 THE WITNESS: Well, talc</p> <p>22 contains asbestos. Whether it</p> <p>23 contains asbestiform asbestos is a</p> <p>24 critical question, yes.</p> <p>25</p>	<p style="text-align: right;">Page 337</p> <p>1 5 milligrams per cubic meter.</p> <p>2 (Glenn Exhibit 27 marked for</p> <p>3 identification.)</p> <p>4 QUESTIONS BY MR. BOWDEN:</p> <p>5 Q. So I'm going to hand you</p> <p>6 Exhibit 27. Take a look at that.</p> <p>7 A. Uh-huh.</p> <p>8 Q. Are you familiar with Johnson &amp;</p> <p>9 Johnson's definition of asbestos?</p> <p>10 MR. HEGARTY: Objection. Form.</p> <p>11 THE WITNESS: I am not.</p> <p>12 QUESTIONS BY MR. BOWDEN:</p> <p>13 Q. I want to go -- this will be --</p> <p>14 I want to go down to this second to the last</p> <p>15 paragraph.</p> <p>16 A. I have not seen this, and it</p> <p>17 might --</p> <p>18 Q. I'm not suggesting that you</p> <p>19 have.</p> <p>20 A. Yeah.</p> <p>21 Q. What I'm asking about here</p> <p>22 is --</p> <p>23 A. Well, what I'm suggesting is to</p> <p>24 have context --</p> <p>25 Q. No, sir, there is no question</p>

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<p>1 pending.</p> <p>2 A. -- to your answers, I may have</p> <p>3 to read it.</p> <p>4 Q. If you want to read -- I'm</p> <p>5 sorry, if you want to read the document, go</p> <p>6 ahead. Take your time.</p> <p>7 A. Okay. Okay. I think I've read</p> <p>8 enough now to have the context.</p> <p>9 I wouldn't agree with their</p> <p>10 definition of asbestos.</p> <p>11 Q. Okay. I'm not asking you to</p> <p>12 agree with it.</p> <p>13 A. Yeah.</p> <p>14 Q. But in the context of this</p> <p>15 discussion --</p> <p>16 A. Right.</p> <p>17 Q. -- this is how I'm defining it,</p> <p>18 is Johnson &amp; Johnson's definition.</p> <p>19 A. This is their definition,</p> <p>20 correct.</p> <p>21 MR. HEGARTY: Objection.</p> <p>22 QUESTIONS BY MR. BOWDEN:</p> <p>23 Q. "Asbestos is defined to be the</p> <p>24 fibrous serpentine chrysotile and the fibrous</p> <p>25 forms of the amphibole group as represented</p>	<p>1 the date I'm not committed to because I think</p> <p>2 even in your correspondence with them you say</p> <p>3 may have been 1975 or choose whatever date</p> <p>4 you want in the 1970s.</p> <p>5 Prior to that, some of the</p> <p>6 studies that were done may have included</p> <p>7 women who were exposed to talcum-based</p> <p>8 products which contained asbestos?</p> <p>9 A. I don't know that to be a fact</p> <p>10 at all.</p> <p>11 MR. DONATH: Objection. Form.</p> <p>12 MR. HEGARTY: Objection.</p> <p>13 THE WITNESS: I believe the</p> <p>14 Stanton paper was published before</p> <p>15 that, his hallmark paper on</p> <p>16 implantation at the pleura of asbestos</p> <p>17 and other products, and none of the</p> <p>18 talcs produced a significant number of</p> <p>19 tumors in experimental animals.</p> <p>20 QUESTIONS BY MR. BOWDEN:</p> <p>21 Q. Well, I'm asking you a broader</p> <p>22 question, and maybe it's a -- it's the way</p> <p>23 that I'm phrasing it that's confusing.</p> <p>24 A. Uh-huh.</p> <p>25 Q. It would be unacceptable to</p>
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<p>1 by amosite, anthophyllite, crocidolite,</p> <p>2 tremolite asbestos and actinolite."</p> <p>3 Do you see that there?</p> <p>4 A. Yeah, I read that in here, yes.</p> <p>5 I'm not sure -- oh, there's the paragraph,</p> <p>6 okay. I got it, yeah.</p> <p>7 Q. Okay. My question to you is:</p> <p>8 When you were discussing with Dr. Muscat that</p> <p>9 talcum powder products were free of asbestos</p> <p>10 as of 1975, you were meaning that there was</p> <p>11 no asbestos whatsoever in there, correct?</p> <p>12 MR. DONATH: Objection to form.</p> <p>13 THE WITNESS: I meant --</p> <p>14 MR. BILLINGS-KANG: Objection.</p> <p>15 THE WITNESS: -- there was no</p> <p>16 asbestiform asbestos in it.</p> <p>17 QUESTIONS BY MR. BOWDEN:</p> <p>18 Q. Right.</p> <p>19 A. Yeah.</p> <p>20 Q. And that's an important</p> <p>21 distinction, correct?</p> <p>22 A. Yes.</p> <p>23 MR. DONATH: Objection.</p> <p>24 QUESTIONS BY MR. BOWDEN:</p> <p>25 Q. Because prior to 1975 -- and</p>	<p>1 have even one fiber of asbestos in talcum</p> <p>2 products, correct?</p> <p>3 MR. DONATH: Objection.</p> <p>4 THE WITNESS: One asbestiform</p> <p>5 fiber, yes. It would not be a good</p> <p>6 business, right.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. It would not be acceptable?</p> <p>9 MR. DONATH: Objection.</p> <p>10 THE WITNESS: It would -- it</p> <p>11 would not be acceptable, yes, if</p> <p>12 you -- if you have a protocol that</p> <p>13 would determine that, yes.</p> <p>14 QUESTIONS BY MR. BOWDEN:</p> <p>15 Q. Okay. And if there were a</p> <p>16 fiber of asbestos in talcum-based products,</p> <p>17 that would provide a biologically plausible</p> <p>18 mechanism for the observance of the increased</p> <p>19 risk in these studies, correct?</p> <p>20 MR. DONATH: Objection to form.</p> <p>21 MR. HEGARTY: Objection. Form.</p> <p>22 THE WITNESS: I know it</p> <p>23 certainly would in lung disease. I</p> <p>24 would suspect it biologically</p> <p>25 plausible that it would also do</p>

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<p>1 similar mechanism of disease in other 2 tissues and organs, so I would expect 3 it would. 4 QUESTIONS BY MR. BOWDEN: 5 Q. And when you say "expect it 6 would," we're talking about ovarian cells? 7 A. Ovarian cancer, yes. 8 In fact, Brooke Mossman's study 9 showed that, that asbestos, true asbestos, 10 was the only mineral she -- the only particle 11 she tested that showed a positive response to 12 genetic microarray. 13 Q. So now we've talked a little 14 bit about -- and I'm still on IARC, but we're 15 changing gears a little bit from our asbestos 16 discussion. 17 Okay? 18 A. Yes. 19 MR. BOWDEN: I want to go to 20 P1.66, Mr. Smith. 21 (Glenn Exhibit 28 marked for 22 identification.) 23 QUESTIONS BY MR. BOWDEN: 24 Q. Mark this as Exhibit 28 for 25 you.</p>	<p>1 those people weren't actually there, though. 2 These were -- 3 A. No. They were on the phone 4 call. 5 Q. And there's a little bit of a 6 space there, and you can see it looks like 7 the people that are actually on the ground 8 were -- 9 A. Right. 10 Q. -- yourself, Mr. Parks and 11 Mr. Turner? 12 MR. DONATH: Objection to form. 13 THE WITNESS: That's correct. 14 That's correct. 15 QUESTIONS BY MR. BOWDEN: 16 Q. And Dr. Huncharek was on the 17 phone for MRG, right? 18 A. Yes. 19 Q. Steven Mann for Johnson &amp; 20 Johnson? 21 A. He was actually -- he says he 22 was representing himself from the Marshfield 23 Clinic, the hospital he worked at. 24 Q. Okay. Well, I mean, at the 25 time he was under a contract with guys --</p>
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<p>1 A. Thank you. 2 Q. You can see at the top here 3 these are meeting minutes from the talc 4 section teleconference, IMA-North America in 5 conjunction with IMA-Europe. 6 Do you see that? 7 A. Yes. 8 Q. And they're holding a joint 9 meeting, Tuesday, February 14th, and this is 10 the day that the vote came down, right? 11 A. Yes. 12 Q. Okay. And let's look at the 13 participants there. You have the operations 14 room. 15 Do you see yourself as listed? 16 A. Yes. 17 Q. Crowell &amp; Moring, LLP. 18 Eric Turner, Luzenac, is 19 listed? 20 A. Yes. 21 Q. Linda Loretz, CTFA, is listed? 22 A. Yes. 23 Q. Michele Wyart, IMA-Europe? 24 A. Yes. 25 Q. And you're telling me that</p>	<p>1 with Crowell &amp; Moring through Meta-Analysis 2 Research Group, right? 3 MR. HEGARTY: Objection to 4 form. 5 MR. DONATH: Objection. Form. 6 QUESTIONS BY MR. BOWDEN: 7 Q. But you're right, it does say 8 Marshfield Clinic. 9 A. Yeah. 10 Q. Then if we go down where -- 11 it's the first -- second paragraph that says 12 "Eric Turner." 13 A. Yes. 14 Q. "Eric Turner expressed his 15 warmest thanks to Drs. Gunter Oberdörster and 16 Joshua Muscat, who both played a key role in 17 the defense of the talc dossier," right? 18 A. Yes. 19 Q. "And their respective 20 subgroups, as well as to the whole supportive 21 group who assisted during the week and even 22 months and years," right? 23 A. Yes. 24 Q. So this is the culmination of 25 effort that had been going on for weeks,</p>

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<p>1 months, and supporting IMA-North America</p> <p>2 meeting minutes, years, right?</p> <p>3 MR. DONATH: Objection to form.</p> <p>4 MR. HEGARTY: Objection. Form.</p> <p>5 THE WITNESS: Well, looking at</p> <p>6 the talc ovarian cancer on the whole,</p> <p>7 yes, it's been that long.</p> <p>8 QUESTIONS BY MR. BOWDEN:</p> <p>9 Q. And if we go to the last page,</p> <p>10 66.3.</p> <p>11 A. Yes.</p> <p>12 Q. "The participants discussed the</p> <p>13 need for further developing research to</p> <p>14 address gaps, and Eric Turner emphasized that</p> <p>15 RTM" --</p> <p>16 That's Rio Tinto?</p> <p>17 A. Yes.</p> <p>18 Q. Is that Luzenac, right?</p> <p>19 A. Yes.</p> <p>20 MR. DONATH: Objection to form.</p> <p>21 QUESTIONS BY MR. BOWDEN:</p> <p>22 Q. "Eric Turner emphasized that</p> <p>23 RTM will challenge the issue to demonstrate</p> <p>24 that talc is a very safe material through</p> <p>25 research projects confided to independent</p>	<p>1 written?</p> <p>2 A. Yes.</p> <p>3 Q. And then underneath Situation</p> <p>4 Analysis --</p> <p>5 A. Yes.</p> <p>6 Q. -- about halfway through that</p> <p>7 paragraph where it starts "IARC"?</p> <p>8 A. Yeah.</p> <p>9 Q. "IARC has not set or enforce</p> <p>10 policy or legislation aimed at controlling</p> <p>11 carcinogens, but it is a highly influential</p> <p>12 agency. For example, in the United States,</p> <p>13 many agencies automatically recalibrate their</p> <p>14 regulations based on IARC findings."</p> <p>15 Do you see that?</p> <p>16 MR. DONATH: Objection to form.</p> <p>17 THE WITNESS: Yes, I do see</p> <p>18 that, and it remind -- reminds me that</p> <p>19 IARC -- there were -- their process is</p> <p>20 looked at -- at identification of</p> <p>21 carcinogens, the first step in risk</p> <p>22 assessment.</p> <p>23 QUESTIONS BY MR. BOWDEN:</p> <p>24 Q. If you go to page 3, there's a</p> <p>25 section entitled "Stakeholders."</p>
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<p>1 scientists."</p> <p>2 Do you see that there?</p> <p>3 A. Yes.</p> <p>4 Q. And if we go back again to the</p> <p>5 first page, what we're talking about is the</p> <p>6 defense of talc, right?</p> <p>7 MR. DONATH: Objection to form.</p> <p>8 THE WITNESS: That was her</p> <p>9 terminology, yes.</p> <p>10 (Glenn Exhibit 29 marked for</p> <p>11 identification.)</p> <p>12 QUESTIONS BY MR. BOWDEN:</p> <p>13 Q. Okay. Let's go to P1.0188.</p> <p>14 I'm going to mark this for you as Exhibit</p> <p>15 Number 29. This is P1.0188.</p> <p>16 Now, you can see this is</p> <p>17 Rio Tinto Minerals, right?</p> <p>18 A. Yes.</p> <p>19 Q. And this is a memorandum</p> <p>20 revised February 15, 2006.</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. And it's regarding IARC</p> <p>24 strategy and initial communications.</p> <p>25 Do you see where that's</p>	<p>1 Do you see that?</p> <p>2 A. Yes. Yes.</p> <p>3 Q. "A critical aspect of this</p> <p>4 mitigation plan involves creating alliances</p> <p>5 with and communicating clearly and</p> <p>6 consistently to key stakeholders,</p> <p>7 including -- "</p> <p>8 Do you see where that's listed?</p> <p>9 A. Yes.</p> <p>10 Q. -- "Rio Tinto Minerals</p> <p>11 employees, Rio Tinto Minerals customers" --</p> <p>12 Those would be people like</p> <p>13 Johnson &amp; Johnson, right?</p> <p>14 MR. DONATH: Objection to form.</p> <p>15 THE WITNESS: Uh-huh, yes.</p> <p>16 QUESTIONS BY MR. BOWDEN:</p> <p>17 Q. Okay. -- "government officials</p> <p>18 and regulators"?</p> <p>19 A. Johnson &amp; Johnson and others,</p> <p>20 yes.</p> <p>21 Q. Sure, I didn't mean for it to</p> <p>22 be an exclusive group, but that's one of</p> <p>23 them, right?</p> <p>24 A. Yes.</p> <p>25 Q. "Government officials and</p>

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<p style="text-align: right;">Page 350</p> <p>1 regulators"?</p> <p>2 A. Yes.</p> <p>3 Q. "Industrial minerals, chemical</p> <p>4 and other trade organizations"?</p> <p>5 A. Yes.</p> <p>6 Q. And that's things like IMA,</p> <p>7 CTFA, NISA, right?</p> <p>8 A. Right.</p> <p>9 Q. "News media"?</p> <p>10 A. You skipped the medical</p> <p>11 community, including leading academics.</p> <p>12 Q. I didn't mean to. I'm going to</p> <p>13 do that, too.</p> <p>14 A. Well, I think that's an</p> <p>15 important --</p> <p>16 Q. "The medical community,</p> <p>17 including leading academics," right?</p> <p>18 A. Correct.</p> <p>19 Q. And those are what they've</p> <p>20 identified as the stakeholders, right?</p> <p>21 A. That was in this document, yes.</p> <p>22 Q. And then the objectives --</p> <p>23 "immediate objectives are to," do you see</p> <p>24 where that's written?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 352</p> <p>1 A. Yes.</p> <p>2 Q. And so we've discussed that</p> <p>3 IARC is a difficult agency to influence,</p> <p>4 right?</p> <p>5 MR. DONATH: Objection.</p> <p>6 THE WITNESS: It can be.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. And so when IARC recategorized</p> <p>9 talc as a 2B, non-asbestiform talc as a 2B,</p> <p>10 carcinogen your client the next day issues</p> <p>11 immediate objectives to establish a plan for</p> <p>12 influencing regulators on how they apply the</p> <p>13 IARC findings, correct?</p> <p>14 MR. DONATH: Objection to form.</p> <p>15 MR. BILLINGS-KANG: Objection</p> <p>16 to form.</p> <p>17 MR. HEGARTY: Objection to</p> <p>18 form.</p> <p>19 THE WITNESS: There's some</p> <p>20 other bullet points that seem equally</p> <p>21 important, like demonstrate the</p> <p>22 employees --</p> <p>23 QUESTIONS BY MR. BOWDEN:</p> <p>24 Q. Well, they come afterwards,</p> <p>25 right?</p>
<p style="text-align: right;">Page 351</p> <p>1 Q. Number one objective is</p> <p>2 "understand the impact of potential</p> <p>3 categorization on the business in order to</p> <p>4 assess risk and create mitigation plans."</p> <p>5 MR. DONATH: Objection to form.</p> <p>6 THE WITNESS: Yes.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. They're talking about a</p> <p>9 business strategy, right?</p> <p>10 MR. DONATH: Objection to form.</p> <p>11 THE WITNESS: It sounds like</p> <p>12 that. I wasn't a party to this</p> <p>13 discussion.</p> <p>14 QUESTIONS BY MR. BOWDEN:</p> <p>15 Q. I'm not saying that you were,</p> <p>16 sir.</p> <p>17 A. It might have helped if I'd</p> <p>18 seen this document before now, but --</p> <p>19 Q. Well, we're going to go through</p> <p>20 it together.</p> <p>21 A. Okay.</p> <p>22 Q. The second bullet point says,</p> <p>23 "Establish a plan for influencing regulators</p> <p>24 on how they apply the IARC findings."</p> <p>25 Do you see that?</p>	<p style="text-align: right;">Page 353</p> <p>1 MR. DONATH: Objection to form.</p> <p>2 THE WITNESS: Yeah, they do,</p> <p>3 but they seem important to the context</p> <p>4 of what we're talking about.</p> <p>5 QUESTIONS BY MR. BOWDEN:</p> <p>6 Q. But the number one objective on</p> <p>7 here, the first listed objective, is to</p> <p>8 understand the impact to the business, right?</p> <p>9 MR. DONATH: Objection to form.</p> <p>10 THE WITNESS: Correct.</p> <p>11 MR. BILLINGS-KANG: Objection.</p> <p>12 QUESTIONS BY MR. BOWDEN:</p> <p>13 Q. The second objective listed</p> <p>14 underneath here is to "establish a plan for</p> <p>15 influencing regulators and how they apply the</p> <p>16 IARC findings," correct?</p> <p>17 MR. DAVANT: Same objection.</p> <p>18 THE WITNESS: And these bullet</p> <p>19 points, they may not list any</p> <p>20 priority.</p> <p>21 QUESTIONS BY MR. BOWDEN:</p> <p>22 Q. Okay.</p> <p>23 You don't know that, do you?</p> <p>24 A. No, I don't. I'm just saying</p> <p>25 it could be.</p>

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<p>1 Q. Let's turn to page -- and</p> <p>2 underneath the stakeholders, you don't see</p> <p>3 anywhere where it's listed as consumers,</p> <p>4 right?</p> <p>5 A. Well, news media certainly</p> <p>6 would get out to consumers, wouldn't it?</p> <p>7 Q. Not directly, though, right?</p> <p>8 MR. DONATH: Objection to form.</p> <p>9 THE WITNESS: Well --</p> <p>10 QUESTIONS BY MR. BOWDEN:</p> <p>11 Q. I mean, that's -- that's --</p> <p>12 A. I think it would. It would get</p> <p>13 out directly to consumers by reading</p> <p>14 newspaper articles.</p> <p>15 Q. Wouldn't it be easier to just</p> <p>16 put it on the bottle?</p> <p>17 MR. DONATH: Objection to form.</p> <p>18 THE WITNESS: I don't know what</p> <p>19 they put on the bottle.</p> <p>20 QUESTIONS BY MR. BOWDEN:</p> <p>21 Q. Wouldn't that be the most</p> <p>22 direct form --</p> <p>23 A. I'm just saying the news media,</p> <p>24 that would be one way of --</p> <p>25 MR. BILLINGS-KANG: Objection</p>	<p>1 The hazard communication</p> <p>2 standard, which is a workplace</p> <p>3 standard, does not require that 2Bs, I</p> <p>4 don't believe requires 2Bs, to be put</p> <p>5 on the label.</p> <p>6 QUESTIONS BY MR. BOWDEN:</p> <p>7 Q. Am I understanding you</p> <p>8 correctly to say that it wasn't done, and</p> <p>9 you're not required to do it?</p> <p>10 MR. DONATH: Objection.</p> <p>11 THE WITNESS: It was not done.</p> <p>12 I'm not sure what the requirement of</p> <p>13 FDA was.</p> <p>14 QUESTIONS BY MR. BOWDEN:</p> <p>15 Q. You do agree with me, though,</p> <p>16 that that would be an effective way of</p> <p>17 relaying to consumers that talc was now a</p> <p>18 potential human carcinogen, by putting it</p> <p>19 directly on the bottle?</p> <p>20 MR. DONATH: Objection to form.</p> <p>21 THE WITNESS: Product labeling</p> <p>22 can be important in passing that type</p> <p>23 of information downstream, yes.</p> <p>24 QUESTIONS BY MR. BOWDEN:</p> <p>25 Q. Let's go to page 5.</p>
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<p>1 the form.</p> <p>2 THE WITNESS: Distributing it</p> <p>3 to the consumer. I would think that</p> <p>4 if some lady was using talc for</p> <p>5 perineal application and she sees a</p> <p>6 headline "body talc may cause cancer,"</p> <p>7 she would certainly read it.</p> <p>8 QUESTIONS BY MR. BOWDEN:</p> <p>9 Q. What about putting it on the</p> <p>10 bottle directly so that the consumers know?</p> <p>11 MR. BILLINGS-KANG: Objection</p> <p>12 to form.</p> <p>13 MR. DONATH: Objection to form.</p> <p>14 THE WITNESS: I don't know if</p> <p>15 there's a requirement to do that.</p> <p>16 QUESTIONS BY MR. BOWDEN:</p> <p>17 Q. I'm not asking if there's a</p> <p>18 requirement.</p> <p>19 Would that accomplish it?</p> <p>20 MR. BILLINGS-KANG: Objection</p> <p>21 to form.</p> <p>22 MR. DONATH: Same objection.</p> <p>23 THE WITNESS: I don't think the</p> <p>24 decision of IARC was sufficient to do</p> <p>25 that.</p>	<p>1 A. Okay.</p> <p>2 Q. You with me?</p> <p>3 A. Yes.</p> <p>4 Q. Underneath the large redacted</p> <p>5 section --</p> <p>6 A. Yes.</p> <p>7 Q. Underneath it says "legal" and</p> <p>8 then it's redacted.</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And then it says, "Science, Sue</p> <p>12 Hubbard, team lead," right?</p> <p>13 A. Yes.</p> <p>14 Q. And it says underneath that,</p> <p>15 "Contest the IARC process as using the 93</p> <p>16 monograph as deeply flawed and skewed by</p> <p>17 academic bias."</p> <p>18 Do you see that?</p> <p>19 A. That's what is written, yes.</p> <p>20 Q. "Actions: Develop a group of</p> <p>21 academics who can publish and otherwise</p> <p>22 communicate on this issue," right?</p> <p>23 A. Yes.</p> <p>24 Q. "2, develop long-term science</p> <p>25 strategy to enhance the body of research</p>

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<p>1 examining the supposed association between 2 talc use and carcinogenicity." 3 Do you see where that's 4 written? 5 A. Yes. 6 Q. "Sue Hubbard, Rich Zazenski, 7 plus internal/external legal counsel, date, 8 question mark." 9 Do you see that? 10 A. Yes. 11 Q. Last bullet point there -- 12 A. I might add, it doesn't say 13 Crowell &amp; Moring. 14 Q. Oh, okay. Let's go to the very 15 bottom. 16 A. Oh, okay. 17 Q. "Team to be set up compromising 18 {sic} Sue Hubbard, Rich Zazenski, Michelle 19 Frigjier, using outside help, Bob Glenn, 20 Crowell &amp; Moring." 21 Do you see that there? 22 A. I see that. 23 Q. Okay. So it is talking about 24 you? 25 A. Yeah. And if I'd have seen</p>	<p>1 impression that you feel like that's my 2 fault, that they didn't share it with you. 3 A. I mean, if you'd have given it 4 to me before I came in here today, I wouldn't 5 have made that mistake of saying I wasn't 6 part of, included, involved in their 7 strategy. 8 By the way, they never followed 9 up with me on this. 10 Q. They never followed up with 11 you? 12 A. I don't recall them ever 13 following up regarding to this. 14 Q. Okay. 15 A. The -- we went ahead with the 16 publications of the articles, and we went 17 ahead with Brooke Mossman's work, which IMA 18 funded. 19 We had a proposal for Luzenac 20 to do that genetic microarray, and they did 21 not fund it. 22 Q. I tell you what, let's talk 23 about that next. 24 A. All right. We also had a 25 proposal from Dr. -- I'm drawing a blank on</p>
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<p>1 this before, I would have known that. If I 2 had seen this before today. 3 Q. You know that as in the course 4 of your employment through Crowell &amp; Moring? 5 A. I never saw this document until 6 today. 7 Q. Oh, okay. 8 A. They didn't share it with me. 9 Where did it come from in 10 discovery? Imerys? 11 Q. Your client. 12 A. Imerys? 13 Q. Yes, sir. You see on the 14 bottom right there -- 15 A. Yes. 16 Q. -- it says "Imerys"? 17 A. Right. Right. But they 18 didn't -- they didn't give me everything in 19 their files, Counsel, I'm sure. 20 Q. I understand, but we've also 21 just covered that you didn't ask for 22 everything either, right? 23 A. No, I didn't ask for everything 24 they had in their files. 25 Q. Okay. I just get the</p>	<p>1 his name now. A well-known epidemiologist to 2 do some work. They did not fund that. 3 Ken -- Ken Rothman. 4 Q. Do you feel that Imerys didn't 5 do studies that they ought to have done? 6 MR. DONATH: Objection to form. 7 THE WITNESS: No, I didn't say 8 that. They -- for some reason they 9 decided not to fund some studies. 10 VIDEOGRAPHER: The time is now 11 3:01. Going off the record. 12 (Off the record at 3:01 p.m.) 13 VIDEOGRAPHER: Okay. The time 14 is now 3:10. Back on the record. 15 QUESTIONS BY MR. BOWDEN: 16 Q. Left off talking about Sue 17 Hubbard, and then we were talking about how 18 one her tasks as a team lead was to develop 19 long-term science to enhance the body of 20 research, examining the association between 21 talc use and ovarian cancer, right? 22 A. Yeah. 23 Q. And you had said that for some 24 reason there were some studies they decided 25 not to fund, correct?</p>



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<p>1 A. Yes.</p> <p>2 Q. All right. So let's switch</p> <p>3 gears and start talking about some of those</p> <p>4 studies.</p> <p>5 A. Okay.</p> <p>6 (Glenn Exhibit 30 marked for</p> <p>7 identification.)</p> <p>8 QUESTIONS BY MR. BOWDEN:</p> <p>9 Q. And I'm going to show you</p> <p>10 another document produced by Imerys. This</p> <p>11 will be Exhibit Number 30.</p> <p>12 Let's go ahead and pull out the</p> <p>13 top, who this is from.</p> <p>14 A. Yes.</p> <p>15 Q. You see this is Ms. Hubbard,</p> <p>16 right?</p> <p>17 A. Yes. Yes.</p> <p>18 Q. And this is to Mr. Zazenski,</p> <p>19 right, and this is June 9, 2006.</p> <p>20 Do you see that?</p> <p>21 A. Yes.</p> <p>22 Q. It says, "Rich, we are meeting</p> <p>23 with Bob Glenn on Tuesday to discuss the talc</p> <p>24 research, et cetera. What is our contractual</p> <p>25 relationship with him, and is he under a</p>	<p>1 A. Yes, I do.</p> <p>2 Q. They're talking about value.</p> <p>3 And we've seen in those meeting minutes from</p> <p>4 February, the one where she was tasked with</p> <p>5 being the team lead for developing science,</p> <p>6 that some of the considerations were for</p> <p>7 business considerations, right?</p> <p>8 MR. DONATH: Objection to form.</p> <p>9 QUESTIONS BY MR. BOWDEN:</p> <p>10 Q. Are you having difficulty</p> <p>11 hearing?</p> <p>12 A. Well, just repeat that. The</p> <p>13 truck was a little loud and the other things,</p> <p>14 but --</p> <p>15 MR. BOWDEN: Counsel, would you</p> <p>16 mind -- I'm sorry.</p> <p>17 THE WITNESS: I'm sorry. Could</p> <p>18 you repeat that?</p> <p>19 QUESTIONS BY MR. BOWDEN:</p> <p>20 Q. I will.</p> <p>21 All right. The question I had</p> <p>22 to you was that they were talking about</p> <p>23 value, whether the research, the scientific</p> <p>24 research, on ovarian cancer and talc use</p> <p>25 would have any value to Imerys, correct?</p>
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<p>1 confidentiality agreement? I need to know</p> <p>2 what we can and can't tell him about the</p> <p>3 future of research."</p> <p>4 Do you see where that's</p> <p>5 written?</p> <p>6 A. Yes.</p> <p>7 Q. "Also, who pays him, and does</p> <p>8 he have a role with Johnson &amp; Johnson?"</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. "Since we are re-review" -- I'm</p> <p>12 sorry, there's an omission there. Let me try</p> <p>13 that again.</p> <p>14 "Since we're reviewing the RTM</p> <p>15 portfolio, I'm going to put some brakes on</p> <p>16 the process related to ovarian cancer until</p> <p>17 we have made an internal decision as to</p> <p>18 whether we support the ovarian use or not and</p> <p>19 we have established what Johnson &amp; Johnson</p> <p>20 are actually going to do. I want to steer</p> <p>21 the conversation around what research would</p> <p>22 still be valuable in this area and look at</p> <p>23 the other non-ovarian work to see what we can</p> <p>24 get going and evaluate that."</p> <p>25 Do you see that?</p>	<p>1 Rio Tinto?</p> <p>2 MR. DONATH: Objection to form.</p> <p>3 THE WITNESS: You got to tell</p> <p>4 me about future research. I'm sorry,</p> <p>5 it's so hot I can't remember what I've</p> <p>6 read. Yeah.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. Okay. And you're not on this</p> <p>9 e-mail, right?</p> <p>10 A. No, and I don't know -- I don't</p> <p>11 ever recall having a follow-up meeting. I'm</p> <p>12 sorry.</p> <p>13 Q. That's okay.</p> <p>14 A. Go ahead.</p> <p>15 Q. Do you agree as of the date of</p> <p>16 that e-mail that there was still -- do you</p> <p>17 agree with me that as of the date of that</p> <p>18 e-mail that there was valuable scientific</p> <p>19 research that could still be done?</p> <p>20 A. Yes. Being a researcher, I'd</p> <p>21 probably always answer that in the</p> <p>22 affirmative.</p> <p>23 Q. What research did you think</p> <p>24 would be useful at that time?</p> <p>25 A. I was still interested in -- I</p>



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<p>1 still would liked to have done a follow-up of 2 the pleurodesis. I would have liked to have 3 done the genetic microarray, which we did 4 later. I could have -- I don't have them top 5 of my tongue now, but there are others. 6 I think the whole thing is -- 7 Sue suggested in this meeting, one thing that 8 would have been nice is to have a group -- 9 she suggests we have a group convene, 10 possibly under the auspices of the National 11 Academy of Science. And I think that would 12 have been worthwhile, to look at what are the 13 critical knowledge gaps that need to be 14 filled. 15 Q. And they never did it, right? 16 MR. DONATH: Objection to form. 17 MR. DAVANT: Objection. 18 THE WITNESS: I don't think 19 they did any of the things in this -- 20 I'm not sure. 21 QUESTIONS BY MR. BOWDEN: 22 Q. And J&amp;J didn't do it either, to 23 your knowledge, right? 24 MR. HEGARTY: Objection to 25 form.</p>	<p>1 MR. DONATH: Foundation. 2 QUESTIONS BY MR. BOWDEN: 3 Q. All right. It's an important 4 public health issue back in the 1970s, right? 5 MR. DONATH: Objection to form. 6 MR. DAVANT: Objection to form. 7 QUESTIONS BY MR. BOWDEN: 8 Q. Well, ovarian cancer has always 9 been an important -- 10 A. Ovarian cancer certainly is an 11 important public health issue. 12 Q. Right. 13 And it's still an important 14 health issue, right? 15 A. I don't know whether talc was 16 an important risk factor for it, and I think 17 that's what we should have found out. 18 Q. You think they should have 19 found it out then? 20 MR. HEGARTY: Objection to 21 form. 22 MR. DONATH: Objection to form. 23 THE WITNESS: Again, I'm a 24 researcher, and I won't -- I want the 25 best research applied to these</p>
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<p>1 MR. DONATH: Objection. 2 THE WITNESS: As I say, I don't 3 recall anything coming out of the -- 4 this, and I don't recall anything 5 coming out of this. In fact, I don't 6 even know if we ever met. I can't 7 remember. 8 I know Sue Hubbard, I met her 9 once or so, but I don't think -- she 10 says we're meeting with Bob Glenn, but 11 I don't recall the meeting. 12 QUESTIONS BY MR. BOWDEN: 13 Q. Okay. And this was an 14 important issue that had been going on for 15 40 years, right, since the -- at least 1970s? 16 MR. DONATH: Objection to form. 17 MR. HEGARTY: Objection to 18 form. 19 THE WITNESS: Yeah, it -- it 20 really -- probably more fair to say it 21 gathered momentum in the early '80s. 22 QUESTIONS BY MR. BOWDEN: 23 Q. Okay. 24 A. It was first recognized in '72, 25 I believe, by Griffith.</p>	<p>1 questions to say that we can answer 2 them. And often if you do get groups 3 together and you concentrate on what 4 are the critical knowledge gaps in the 5 literature, and which ones need to be 6 filled and which -- what's the 7 priority, you can make some progress. 8 But that didn't happen. 9 (Glenn Exhibit 31 marked for 10 identification.) 11 QUESTIONS BY MR. BOWDEN: 12 Q. Okay. I'm going to mark for 13 you Exhibit Number 31. 14 A. All right. 15 Q. Do you have a copy in front of 16 you, sir? 17 A. Yes, I do now. 18 Q. This is a little difficult to 19 read, especially with the red lining. 20 A. Yeah. 21 Q. I'm going to put it up on the 22 screen for you. 23 A. Okay. 24 Q. All right. So this will be a 25 little bit tricky because I'm left-handed and</p>



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<p style="text-align: right;">Page 370</p> <p>1 reaching over, so...</p> <p>2 A. I can work from this.</p> <p>3 Q. I know, but I want it to be</p> <p>4 picked up, too, for the camera, so I'll walk</p> <p>5 through it here with you?</p> <p>6 A. Yeah. Oh, okay. I understand.</p> <p>7 Q. You see at the top there it</p> <p>8 says July 20, 2006?</p> <p>9 A. Yes.</p> <p>10 Q. And this was a letter on</p> <p>11 Rio Tinto Minerals' letterhead.</p> <p>12 Do you see that?</p> <p>13 A. Correct.</p> <p>14 Q. And you can see that this</p> <p>15 document is signed -- or is prepared for Eric</p> <p>16 Turner.</p> <p>17 Do you see that there?</p> <p>18 MR. DONATH: Objection to form.</p> <p>19 THE WITNESS: Prepared by Eric</p> <p>20 Turner? Okay. I don't see that</p> <p>21 paragraph.</p> <p>22 QUESTIONS BY MR. BOWDEN:</p> <p>23 Q. Actually, I'm sorry, I'm on the</p> <p>24 wrong page. Let's go back.</p> <p>25 A. Okay. I was thinking that.</p>	<p style="text-align: right;">Page 372</p> <p>1 written?</p> <p>2 A. Yes.</p> <p>3 Q. "Due to the considerable costs</p> <p>4 involved and deadlines no longer a factor,</p> <p>5 Luzenac, Rio Tinto Minerals, made the</p> <p>6 decision that the potential value of this</p> <p>7 study was greatly diminished and did not</p> <p>8 warrant any further pursuit at this time."</p> <p>9 Do you see that?</p> <p>10 A. Yes, I do.</p> <p>11 Q. "Considerable costs and the</p> <p>12 deadline no longer being a factor."</p> <p>13 The deadline that they're</p> <p>14 talking about is the publication date prior</p> <p>15 to having it be published prior to the IARC</p> <p>16 proceeding?</p> <p>17 A. It was the IARC, yes.</p> <p>18 Q. And it was going to cost money,</p> <p>19 right?</p> <p>20 A. Yes.</p> <p>21 MR. DONATH: Objection to form.</p> <p>22 QUESTIONS BY MR. BOWDEN:</p> <p>23 Q. And there's no consideration</p> <p>24 out there in that for the ones that you've</p> <p>25 just talked about, advancing the scientific</p>
<p style="text-align: right;">Page 371</p> <p>1 Q. Showing you the wrong cover</p> <p>2 page there.</p> <p>3 A. All right.</p> <p>4 Q. It looks like two documents</p> <p>5 together.</p> <p>6 A. Yeah.</p> <p>7 Q. So go with me to page 3 is</p> <p>8 where I meant to be at.</p> <p>9 A. The Mark -- the Mark Ellis?</p> <p>10 Q. Right. Mark Ellis.</p> <p>11 And he is the president</p> <p>12 IMA-North America, right?</p> <p>13 A. Yes.</p> <p>14 Q. And down here where it says,</p> <p>15 "When IARC concluded and reclassified" --</p> <p>16 "concluded their review and classified</p> <p>17 perineal use of talc-based powders as a 2B</p> <p>18 carcinogen, we began to question the value of</p> <p>19 proceeding any further with the Mossman</p> <p>20 study."</p> <p>21 Do you see that there?</p> <p>22 A. Yes.</p> <p>23 Q. "To put it in the vernacular,</p> <p>24 the horse had already left the barn."</p> <p>25 Do you see where that's</p>	<p style="text-align: right;">Page 373</p> <p>1 knowledge, right?</p> <p>2 MR. DONATH: Objection to form.</p> <p>3 MR. HEGARTY: Objection. Form.</p> <p>4 THE WITNESS: I'm sorry, say</p> <p>5 that again?</p> <p>6 QUESTIONS BY MR. BOWDEN:</p> <p>7 Q. There's no mention in here as</p> <p>8 one of the considerations --</p> <p>9 A. They didn't --</p> <p>10 Q. -- is not consumers, right?</p> <p>11 A. No. They didn't mention that,</p> <p>12 no.</p> <p>13 Q. It was purely based on</p> <p>14 business, true?</p> <p>15 MR. DONATH: Objection to form.</p> <p>16 MR. DAVANT: Objection to form.</p> <p>17 THE WITNESS: It was a business</p> <p>18 decision, yes, evidently. It says so.</p> <p>19 QUESTIONS BY MR. BOWDEN:</p> <p>20 Q. And during this time, J&amp;J,</p> <p>21 Imerys, which was Luzenac, they're all</p> <p>22 coordinating these together, correct?</p> <p>23 MR. HEGARTY: Objection to</p> <p>24 form.</p> <p>25 THE WITNESS: You know, I don't</p>

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<p>1 think I was in the loop here, so I</p> <p>2 don't know who else they were</p> <p>3 coordinating with.</p> <p>4 QUESTIONS BY MR. BOWDEN:</p> <p>5 Q. Uh-huh. And they're talking</p> <p>6 about in this particular document not</p> <p>7 funding, or discontinuing funding, of a study</p> <p>8 which you felt had scientific merit, right?</p> <p>9 MR. DONATH: Object to form.</p> <p>10 THE WITNESS: I thought the</p> <p>11 study did have scientific merit. They</p> <p>12 decided not to fund it.</p> <p>13 QUESTIONS BY MR. BOWDEN:</p> <p>14 Q. I'm sorry. Bear with me,</p> <p>15 Mr. Glenn.</p> <p>16 A. Sure.</p> <p>17 MR. BOWDEN: Let's go off the</p> <p>18 record just for one second.</p> <p>19 VIDEOGRAPHER: The time is now</p> <p>20 3:24. Going off the record.</p> <p>21 (Off the record at 3:24 p.m.)</p> <p>22 VIDEOGRAPHER: Okay. The time</p> <p>23 is now 3:28. Back on the record.</p> <p>24 QUESTIONS BY MR. BOWDEN:</p> <p>25 Q. Going back to this exhibit</p>	<p>1 MR. DAVANT: Object to form.</p> <p>2 MR. DONATH: Object to form.</p> <p>3 MR. HEGARTY: Object to form.</p> <p>4 THE WITNESS: They were</p> <p>5 undergoing -- I was aware they were</p> <p>6 undergoing some changes during that</p> <p>7 period, and in fact I think -- or</p> <p>8 some -- some layoffs.</p> <p>9 QUESTIONS BY MR. BOWDEN:</p> <p>10 Q. Okay. My question to you: Is</p> <p>11 that the only consideration listed in this is</p> <p>12 a business consideration, correct?</p> <p>13 MR. DONATH: Object to form.</p> <p>14 THE WITNESS: A business, yes.</p> <p>15 QUESTIONS BY MR. BOWDEN:</p> <p>16 Q. Correct?</p> <p>17 Do you know if Johnson &amp;</p> <p>18 Johnson picked up the Mossman study?</p> <p>19 MR. HEGARTY: Objection to</p> <p>20 form.</p> <p>21 MR. DAVANT: Objection to form.</p> <p>22 THE WITNESS: I did not</p> <p>23 approach them, but they -- they</p> <p>24 weren't ever asked to fund that study.</p> <p>25</p>
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<p>1 marked Exhibit 31, one of the things that</p> <p>2 they're talking about not funding in this --</p> <p>3 that's the Mossman study, correct?</p> <p>4 A. I believe so, yes.</p> <p>5 Q. Okay. I want to go to the last</p> <p>6 page of this document. It's bullet 3 or</p> <p>7 paragraph number 3?</p> <p>8 A. Yeah. Yeah. Right.</p> <p>9 Q. It says, "Over the last nine</p> <p>10 months, Luzenac has transformed into a new</p> <p>11 company, Rio Tinto Minerals. As a result,</p> <p>12 we're undergoing major changes in our product</p> <p>13 portfolios and business strategies. Our</p> <p>14 limited R&amp;D resources will be applied to</p> <p>15 those products which are essential to our</p> <p>16 stability and growth. Supplying talc for the</p> <p>17 body powder market is rather insignificant --</p> <p>18 is a rather insignificant element in our</p> <p>19 overall product portfolio and does not</p> <p>20 warrant any further sponsorship for research</p> <p>21 projects to support the business."</p> <p>22 Do you see that?</p> <p>23 A. Yes.</p> <p>24 Q. And that's purely a business</p> <p>25 consideration, correct?</p>	<p>1 QUESTIONS BY MR. BOWDEN:</p> <p>2 Q. They didn't, to your knowledge,</p> <p>3 right?</p> <p>4 A. No.</p> <p>5 MR. BOWDEN: Now I want to</p> <p>6 bring up P1.001, Corey.</p> <p>7 (Glenn Exhibit 32 marked for</p> <p>8 identification.)</p> <p>9 QUESTIONS BY MR. BOWDEN:</p> <p>10 Q. I'm going to mark this as</p> <p>11 Exhibit Number 32.</p> <p>12 A. Yes.</p> <p>13 Q. And you're aware that MRG had</p> <p>14 proposed to do 11 different studies, right,</p> <p>15 the Meta-Analysis Research Group?</p> <p>16 MR. HEGARTY: Objection to</p> <p>17 form.</p> <p>18 THE WITNESS: Yes, I -- this</p> <p>19 document doesn't ring bells, but it</p> <p>20 looks like it was something that</p> <p>21 Michael and his group proposed.</p> <p>22 QUESTIONS BY MR. BOWDEN:</p> <p>23 Q. Okay. Were you aware of that</p> <p>24 at the time?</p> <p>25 A. As I say, I don't recall seeing</p>

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<p>1 it, but it obviously -- not obviously, but 2 it's very likely they submitted this to me, 3 looking for research. 4 Q. And was it Luzenac and Johnson 5 &amp; Johnson that asked Meta-Analysis Research 6 Group to revisit their original 11 proposed 7 studies from 2006? 8 MR. HEGARTY: Objection to 9 form. 10 MR. DONATH: Objection to form. 11 THE WITNESS: These studies, I 12 don't know. 13 QUESTIONS BY MR. BOWDEN: 14 Q. Okay. I want to read through 15 these with you. On page 2 -- 16 A. There's no date on this. 17 Q. On page 2 -- 18 A. I don't see a date on this. Is 19 there one? 20 Q. Oh, I'm sorry. I'll represent 21 to you the metadata shows it's from 2008. 22 MR. DAVANT: I'm sorry, what 23 year? 24 MR. BOWDEN: 2008. 25 THE WITNESS: And what</p>	<p>1 this is -- it's a Meta-Analysis Research 2 Group proposal, right? 3 A. Yes. 4 Q. And it's "Perineal talcum use 5 and ovarian cancer risk: A meta-analytic 6 evaluation of the dose-response 7 relationship." 8 Do you see that there? 9 A. Yes. 10 Q. And it says it's prepared for 11 Crowell &amp; Moring -- 12 A. Yes. 13 Q. -- Luzenac, Rio Tinto and J&amp;J 14 Consumer Products Division. 15 Do you see that? 16 A. Yes. 17 Q. And you guys were all still 18 working together at the time of this 19 proposal, right? 20 MR. HEGARTY: Objection to 21 form. 22 QUESTIONS BY MR. BOWDEN: 23 Q. It was sent to all three of you 24 or all four of you? 25 A. Well, I don't recall seeing</p>
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<p>1 data showed it? Oh, the metadata on 2 the document. Okay. 3 MR. BOWDEN: Give me just one 4 second. I might have a different 5 document that would clarify this for 6 you. 7 I'm sorry, can we go off the 8 record for a few minutes, please? 9 VIDEOGRAPHER: The time is now 10 3:33. Going off the record. 11 (Off the record at 3:33 p.m.) 12 VIDEOGRAPHER: Okay. The time 13 is now 3:41. Back on the record. 14 (Glenn Exhibit 33 marked for 15 identification.) 16 QUESTIONS BY MR. BOWDEN: 17 Q. All right. Mr. Glenn, when we 18 left the record we were talking about some of 19 the studies that had not been conducted, 20 right? 21 A. Yes. 22 Q. And so I want to ask you -- I'm 23 going to hand you exhibit number -- what I'm 24 marking as Exhibit Number 33. Okay? 25 And you see that the title of</p>	<p>1 this at the time, but it evidently came to 2 Crowell &amp; Moring. 3 Q. Okay. And if you flip with me 4 to page 109.8? 5 A. Yes. 6 Q. Here it says, "Commercial and 7 scientific significance of the research"? 8 A. Yes. 9 Q. And "significance to the talc 10 industry." 11 Do you see that? 12 A. Yes. 13 Q. "The Hill criteria continue to 14 be the benchmark criteria by which disease 15 causality is based, and a dose-response 16 relationship is almost universally considered 17 a necessary component. If our analysis can 18 show that the risk of ovarian cancer is not 19 related to cumulative perineal talc exposure, 20 it would reduce the likelihood that 21 authoritative bodies would consider talc a 22 human carcinogen or provide evidence to 23 reconsider its designation as an IARC 2B 24 carcinogen." 25 Do you see that?</p>

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<p>1 A. Yes.</p> <p>2 Q. Go to the next page, 109.9.</p> <p>3 A. Okay.</p> <p>4 Q. Middle of the first paragraph</p> <p>5 where it says "further"?</p> <p>6 A. Yes.</p> <p>7 Q. "Further, if it is shown that</p> <p>8 there is no consistent overall trend in risk,</p> <p>9 this would provide a background for future</p> <p>10 claims for a biological mechanism for talc</p> <p>11 carcinogenesis."</p> <p>12 Do you see that there?</p> <p>13 A. Yes.</p> <p>14 Q. Do you agree that this would</p> <p>15 have been an important study to conduct?</p> <p>16 MR. HEGARTY: Objection to</p> <p>17 form.</p> <p>18 MR. DONATH: Objection to form.</p> <p>19 THE WITNESS: I don't know</p> <p>20 enough about this with his proposal,</p> <p>21 but a dose-response study, if it could</p> <p>22 be conducted properly, would have been</p> <p>23 important.</p> <p>24 I'm not sure you would be able</p> <p>25 to put -- put together a sufficient</p>	<p>1 feasibility study, talc China feasibility</p> <p>2 study, Huncharek and Muscat scientific</p> <p>3 standards in epi, Mossman follow-up study,</p> <p>4 Huncharek and Muscat meta-analysis</p> <p>5 dose-response.</p> <p>6 That's the one we just talked</p> <p>7 about, right?</p> <p>8 A. Yes.</p> <p>9 Q. Huncharek and Muscat</p> <p>10 meta-analysis smoking and BMI.</p> <p>11 Do you see that there?</p> <p>12 A. Yes.</p> <p>13 Q. If you turn to page 7 of this</p> <p>14 document, regulatory science project</p> <p>15 proposal?</p> <p>16 A. Just a second. I haven't seen</p> <p>17 this, so I was kind of trying to get a flavor</p> <p>18 for it.</p> <p>19 Q. Okay.</p> <p>20 A. Yes. Okay.</p> <p>21 Q. "Topic, perineal talcum use and</p> <p>22 ovarian cancer risk: A meta-analytic</p> <p>23 evaluation of the dose-response</p> <p>24 relationship."</p> <p>25 Do you see that?</p>
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<p>1 exposure matrix to a perineal</p> <p>2 application of talc.</p> <p>3 QUESTIONS BY MR. BOWDEN:</p> <p>4 Q. To your knowledge, did they</p> <p>5 ever fund this?</p> <p>6 A. No.</p> <p>7 MR. DAVANT: Object to form.</p> <p>8 QUESTIONS BY MR. BOWDEN:</p> <p>9 Q. Neither Crowell &amp; Moring,</p> <p>10 Luzenac, Rio Tinto or Johnson &amp; Johnson?</p> <p>11 MR. DONATH: Objection to form.</p> <p>12 MR. HEGARTY: Objection to</p> <p>13 form.</p> <p>14 THE WITNESS: Not to my</p> <p>15 knowledge.</p> <p>16 (Glenn Exhibit 34 marked for</p> <p>17 identification.)</p> <p>18 QUESTIONS BY MR. BOWDEN:</p> <p>19 Q. Okay. In fact, let's show you</p> <p>20 what I will mark as Exhibit Number 34,</p> <p>21 P1.076. You see this is an internal e-mail</p> <p>22 at Rio Tinto regarding talc studies.</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p> <p>25 Q. And it talks about the talc</p>	<p>1 A. Yes.</p> <p>2 Q. And it goes down, it says at</p> <p>3 the bottom -- or excuse me, in the middle,</p> <p>4 "likelihood of success"?</p> <p>5 A. Yes.</p> <p>6 Q. You see where it says, "High"?</p> <p>7 A. Yes.</p> <p>8 Q. "High since these</p> <p>9 researchers -- researches have extensive</p> <p>10 experience in meta-analysis."</p> <p>11 Do you see that there?</p> <p>12 A. Yes.</p> <p>13 Q. And then if you look down</p> <p>14 underneath "Urgency" --</p> <p>15 A. Yes.</p> <p>16 Q. -- it says, "High due to</p> <p>17 upcoming release of IARC report and Prop 65."</p> <p>18 Do you see that?</p> <p>19 A. Yes.</p> <p>20 Q. But then there's a grid, and</p> <p>21 the grid says, "Business impact: High,</p> <p>22 medium low. Urgency: Low, media, high."</p> <p>23 Do you see that there?</p> <p>24 A. Yes.</p> <p>25 Q. So it's high urgency, medium</p>

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<p>1 business impact, correct?</p> <p>2 A. That's what they have, yes.</p> <p>3 Q. And the reason it's a high</p> <p>4 urgency is that the 93 monograph is going to</p> <p>5 be published in 2010, right?</p> <p>6 MR. DAVANT: Object to form.</p> <p>7 THE WITNESS: I don't think we</p> <p>8 knew when it would come out. We knew</p> <p>9 it would come out. And I -- 2010 was</p> <p>10 this --</p> <p>11 QUESTIONS BY MR. BOWDEN:</p> <p>12 Q. "High due to upcoming release</p> <p>13 of IARC report."</p> <p>14 Do you see where that's</p> <p>15 written?</p> <p>16 A. I don't think we knew it would</p> <p>17 come out. You said 2010. It was published,</p> <p>18 but I don't think we had any advanced notice.</p> <p>19 I'm sorry. Repeat your</p> <p>20 question now?</p> <p>21 Q. If it went to Crowell &amp; Moring,</p> <p>22 who else would it have gone through aside</p> <p>23 from you?</p> <p>24 MR. DAVANT: Object to form.</p> <p>25 MR. DONATH: Object to form.</p>	<p>1 summary internally.</p> <p>2 The Exhibit Number 34 is a</p> <p>3 summary that Imerys has put together, right?</p> <p>4 MR. DONATH: Objection to form.</p> <p>5 MR. BILLINGS-KANG: Objection</p> <p>6 to form.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. And they put the cost at 35,000</p> <p>9 there, right?</p> <p>10 A. Yeah, at 30,000.</p> <p>11 MR. DONATH: Objection to form.</p> <p>12 QUESTIONS BY MR. BOWDEN:</p> <p>13 Q. 35,000?</p> <p>14 A. I'm sorry, what page is that</p> <p>15 on? Page 2?</p> <p>16 Q. Page 7, sir.</p> <p>17 A. 7. Okay.</p> <p>18 MR. BOWDEN: Corey, why don't</p> <p>19 we do a split screen. That might</p> <p>20 help.</p> <p>21 QUESTIONS BY MR. BOWDEN:</p> <p>22 Q. Go to page 7 of 7 of --</p> <p>23 A. Yeah, 35,000 on page 7.</p> <p>24 MR. BOWDEN: Pull up the topic.</p> <p>25 And let's pull out the highlighted</p>
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<p>1 THE WITNESS: I don't see it</p> <p>2 went to Crowell &amp; Moring. I don't --</p> <p>3 does it?</p> <p>4 QUESTIONS BY MR. BOWDEN:</p> <p>5 Q. The MRG research proposal that</p> <p>6 we just looked at, that was --</p> <p>7 A. This one?</p> <p>8 Q. Yes, sir.</p> <p>9 A. Yeah.</p> <p>10 Q. That last exhibit.</p> <p>11 A. Right.</p> <p>12 Q. It says, "This proposal was</p> <p>13 prepared for Crowell &amp; Moring," right?</p> <p>14 A. Yes. I'm sorry, I was looking</p> <p>15 at --</p> <p>16 Q. No, that's --</p> <p>17 A. -- 34.</p> <p>18 Q. Right.</p> <p>19 So it's the same study, though,</p> <p>20 right? What we're looking at in Exhibit 34</p> <p>21 is the same study as the proposal to</p> <p>22 Crowell &amp; Moring in Exhibit Number 33?</p> <p>23 A. What are the costs? It's</p> <p>24 certainly formatted different, so --</p> <p>25 Q. Sure. Well -- and this is a</p>	<p>1 title up here.</p> <p>2 QUESTIONS BY MR. BOWDEN:</p> <p>3 Q. You see those are the same</p> <p>4 topics, right?</p> <p>5 A. Yes.</p> <p>6 Q. Okay.</p> <p>7 MR. BOWDEN: And then, Corey,</p> <p>8 if you'll pull up the middle of</p> <p>9 page 7. How much, 35,000. And then</p> <p>10 page 10 of P1.09, subtotal.</p> <p>11 QUESTIONS BY MR. BOWDEN:</p> <p>12 Q. You see on the screen, sir?</p> <p>13 A. Yeah.</p> <p>14 Q. Those are the same study,</p> <p>15 right?</p> <p>16 MR. DONATH: Object to form.</p> <p>17 THE WITNESS: Same study, yes.</p> <p>18 QUESTIONS BY MR. BOWDEN:</p> <p>19 Q. Right.</p> <p>20 And so this did go to Crowell &amp;</p> <p>21 Moring?</p> <p>22 MR. DAVANT: Object to form.</p> <p>23 THE WITNESS: This one went to</p> <p>24 Crowell &amp; Moring, yes.</p> <p>25</p>

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<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. Right. 3 A. Exhibit 33. 4 Q. Right. 5 And the same study is what's 6 being summarized in Exhibit Number 34, right? 7 A. It appears to be, and that 8 appears to be an abstract of someone from 9 Imerys. 10 Q. Okay. So did it go to you at 11 Crowell &amp; Moring? 12 A. This? 34? 13 Q. 33, the one that says it was to 14 Crowell &amp; Moring. 15 A. I said earlier I don't recall 16 seeing this, but it's -- I liked what he did, 17 see this. 18 Q. And if it didn't go to you, 19 whom else would it have gone to? 20 MR. DAVANT: Object to form. 21 MR. DONATH: I'm going to 22 direct the witness not to answer to 23 the extent it would lead to privileged 24 information. 25</p>	<p>1 Do you see that there? 2 A. Yes. 3 Q. Okay. And the objective -- 4 says, "The objective of the study is to 5 evaluate gene expressions in human ovarian 6 epithelial cells upon exposure to several 7 commercial-type talcs used in the paper 8 industry and in cosmetic products, and to 9 positive and negative control materials." 10 Do you see that there? 11 A. Yes. 12 Q. "Benefits: This study will 13 show that various talcs have low surface 14 reactivity and are nonreactive in the human 15 ovarian epithelial cells," right? 16 A. Yes. 17 Q. That's what Rio Tinto is saying 18 that the benefit of the study would be, 19 correct? 20 A. Yes. 21 MR. DONATH: Objection. Form. 22 THE WITNESS: It's saying it 23 would have a low surface reactivity, 24 yes, and be nonreactive. 25</p>
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<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. Do you know? 3 A. No, I don't, unless Ridge Hall. 4 Q. Okay. 5 A. We were the two that were 6 working for Luzenac, Imerys. 7 Q. Going back to Exhibit 8 Number 34, if you'll go to page 6, which is 9 the preceding page. 10 A. Yeah, one thing. These 11 proposals don't match up with Sue Hubbard's 12 points that she was bringing out that needed 13 to be moved forward. So I don't know why 14 these came out like they did. 15 Q. Are you with me on page 6? 16 A. Of 34. 17 Q. Yes, sir, Exhibit 34. 18 A. I am now, yes. 19 Q. Okay. And do you see where at 20 the top it says, "Topic, a study of gene 21 expressing changes in human ovarian 22 epithelial cells" -- 23 A. Yes. 24 Q. -- "exposed to talc of 25 different sources and mineralogy"?</p>	<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. That's their expectation of the 3 study? 4 MR. DONATH: Objection to form. 5 THE WITNESS: Yes. 6 QUESTIONS BY MR. BOWDEN: 7 Q. And at the end of the benefit 8 section it says, "The results will also 9 provide supportive evidence to IARC to 10 reconsider its designation as a 2B carcinogen 11 should this issue be revisited by IARC." 12 Do you see that there? 13 A. That's what it says, yes. 14 Q. "How much, 97,000"? 15 A. Yes. 16 Q. "Likelihood of success, high, 17 since this is an extension of previous study 18 by Mossman that demonstrated no significant 19 gene expression changes with talc and human 20 ovarian epithelial cells." 21 Do you see where that's 22 written? 23 A. Yes. 24 Q. Is that supposed to be 25 mesothelial cells?</p>



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<p>1 MR. DONATH: Objection. Form.</p> <p>2 THE WITNESS: I think it is.</p> <p>3 QUESTIONS BY MR. BOWDEN:</p> <p>4 Q. I think that's a typo, too.</p> <p>5 A. Yeah, I do, too.</p> <p>6 Q. There was no prior study on --</p> <p>7 A. She did not work with -- to my</p> <p>8 knowledge, Brooke did not work with ovarian</p> <p>9 cells until she did the gene expression work.</p> <p>10 Q. Right.</p> <p>11 Before then it was with human</p> <p>12 mesothelial cells?</p> <p>13 A. Correct.</p> <p>14 Q. Which are what you were</p> <p>15 describing earlier is from the lung area,</p> <p>16 right?</p> <p>17 A. Correct. Yes.</p> <p>18 Q. And so potential challenges, do</p> <p>19 you see where that's written there?</p> <p>20 A. Yes.</p> <p>21 Q. "There is a possibility of</p> <p>22 equivocal results that could suggest adverse</p> <p>23 effects of talc and ovarian cells, such as a</p> <p>24 change in one or two genes in epithelial</p> <p>25 cells exposed -- ovarian epithelial cells</p>	<p>1 today, that that study would have value to</p> <p>2 do, correct?</p> <p>3 MR. DONATH: Objection.</p> <p>4 THE WITNESS: Yes. Yes.</p> <p>5 QUESTIONS BY MR. BOWDEN:</p> <p>6 Q. All right. And you can see at</p> <p>7 the bottom it's prepared by Wayne Ball, 2009?</p> <p>8 A. I don't -- I don't know him.</p> <p>9 Q. I'm not saying you do.</p> <p>10 A. Yeah.</p> <p>11 Q. But he's with Luzenac -- or</p> <p>12 Rio Tinto Materials {sic}, right?</p> <p>13 MR. DONATH: Objection to form.</p> <p>14 THE WITNESS: I don't know. I</p> <p>15 don't know him, and I don't know Keith</p> <p>16 Spearing or Michael -- I may have -- I</p> <p>17 may remember Michael Haraas. I think</p> <p>18 he may have been a toxicologist. But</p> <p>19 the others I don't.</p> <p>20 QUESTIONS BY MR. BOWDEN:</p> <p>21 Q. What about Shripal Sharma?</p> <p>22 A. I've heard that name, but I</p> <p>23 don't remember him being involved -- I wasn't</p> <p>24 involved with him when he -- when I was at</p> <p>25 Crowell &amp; Moring.</p>
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<p>1 exposed to one of the talc products</p> <p>2 evaluated. Prior written approval by RTM</p> <p>3 would be required before publication of the</p> <p>4 results by Dr. Mossman and Fabini."</p> <p>5 Do you see that there?</p> <p>6 A. Yes.</p> <p>7 Q. And so in this study, if they</p> <p>8 fund it, what they're saying is that the</p> <p>9 results would have to receive written</p> <p>10 approval by RTM, Luzenac, before they would</p> <p>11 be allowed to publish, correct?</p> <p>12 MR. DONATH: Objection to form.</p> <p>13 THE WITNESS: That's what it</p> <p>14 says. I wasn't aware of the</p> <p>15 consideration of this.</p> <p>16 QUESTIONS BY MR. BOWDEN:</p> <p>17 Q. Right.</p> <p>18 This was -- this was a company</p> <p>19 internal document, right?</p> <p>20 A. That's correct.</p> <p>21 Q. This analysis was not shared</p> <p>22 with you?</p> <p>23 A. No, it was not.</p> <p>24 Q. Correct?</p> <p>25 And you feel in 2009, and in</p>	<p>1 Q. Okay. You know that he</p> <p>2 actually was the authors for Luzenac of the</p> <p>3 MSDS sheets at the time, right?</p> <p>4 MR. DONATH: Objection to form.</p> <p>5 MR. BILLINGS-KANG: Objection</p> <p>6 to form.</p> <p>7 THE WITNESS: Sharma?</p> <p>8 QUESTIONS BY MR. BOWDEN:</p> <p>9 Q. Mr. Sharma?</p> <p>10 A. I did not know that.</p> <p>11 Q. You did not know that?</p> <p>12 A. No.</p> <p>13 Q. Did you know that he included a</p> <p>14 carcinogen warning on the MSDSs?</p> <p>15 MR. DONATH: Object to form.</p> <p>16 THE WITNESS: I did not know</p> <p>17 that.</p> <p>18 QUESTIONS BY MR. BOWDEN:</p> <p>19 Q. Did you know that he included</p> <p>20 information about talc, cosmetic talc, being</p> <p>21 considered a possible human carcinogen on the</p> <p>22 MSDSs?</p> <p>23 MR. DONATH: Objection to form.</p> <p>24 THE WITNESS: I did not know</p> <p>25 that.</p>

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<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. That information was never 3 shared with you? 4 MR. DONATH: Objection. Form. 5 THE WITNESS: No. 6 QUESTIONS BY MR. BOWDEN: 7 Q. You weren't asked to weigh in 8 on the content of the MSDS at the time it was 9 being written? 10 MR. DONATH: Objection. Form. 11 THE WITNESS: I don't recall 12 ever being asked to look at a MSDS 13 from Rio Tinto, Luzenac. 14 QUESTIONS BY MR. BOWDEN: 15 Q. And to your knowledge, the MSDS 16 that I'm referring to, that was never shared 17 with consumers, to your knowledge, correct? 18 MR. DONATH: Objection. Form. 19 THE WITNESS: I don't know what 20 they distributed. 21 (Glenn Exhibit 35 marked for 22 identification.) 23 QUESTIONS BY MR. BOWDEN: 24 Q. All right. We're going to set 25 that one aside.</p>	<p>1 A. Yes. 2 Q. "Dr. Brooke Mossman, affiliated 3 with the University of Vermont College of 4 Medicine, proposes to compare gene profiling 5 by non-asbestiform talc to that of 6 crocidolite asbestos in human mesothelial and 7 ovarian epithelial cells." 8 A. Correct. 9 Q. Those are two different cell 10 lines, right? 11 A. Yes. 12 Q. Okay. "Little is known about 13 the cellular and molecular effects of talc on 14 cells." 15 Do you see that? 16 A. Yes. 17 Q. "Gene profiling studies have 18 been done on chrysotile asbestos. In 19 contrast to titanium dioxide, chrysotile 20 induces a number of genes linked to 21 inflammation, fibrogenesis and loss of cell 22 control." 23 A. Yes. 24 Q. "Gene profiling increasingly is 25 being used in evaluating the carcinogenic</p>
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<p>1 I'm going to hand you what I'm 2 marking as Exhibit 35. The title of this is 3 called -- it's to the IMA talc section, 4 right? 5 A. Yes. 6 Q. This is from August 15, 2005? 7 A. Correct. 8 Q. Do you recall receiving this? 9 A. Sitting here right now, I 10 don't. I possibly did. 11 Q. And this is talking about 12 "marshalling talc industry resources for IARC 13 monograph 93." 14 Do you see where that's 15 written? 16 A. Yes. 17 Q. So I want to turn to page 3 of 18 this document. 19 A. Okay. Yes. 20 Q. And do you see this last full 21 paragraph of the page starting "Dr. Brooke 22 Mossman"? 23 A. Yes. 24 Q. And again, this is from 2005, 25 right?</p>	<p>1 potential of substances." 2 Do you see that? 3 A. Yes. 4 Q. You agree with that statement, 5 right? 6 A. Yes. 7 Q. Gene profiling was being used 8 increasingly, right? 9 A. Yes, I do. 10 Q. And it had value in 2005, 11 right? 12 MR. DONATH: Objection to form. 13 THE WITNESS: Yes. 14 QUESTIONS BY MR. BOWDEN: 15 Q. You still agree that has value 16 today? 17 A. I do. 18 Q. Okay. "While human 19 epidemiology is likely to be determinative in 20 the working group evaluation of talc, studies 21 that demonstrate the absence of a plausible 22 mechanism of action will cast doubt on causal 23 associations between exposure to talc and 24 cancer." 25 Do you see that?</p>



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<p>1 A. Yes.</p> <p>2 Q. And that's because one of the</p> <p>3 things that you had talked about earlier was</p> <p>4 this Bradford Hill criteria about plausible</p> <p>5 mechanisms.</p> <p>6 Do you remember that?</p> <p>7 A. Biological plausibility.</p> <p>8 Q. Right.</p> <p>9 And that's commonly referred to</p> <p>10 as biological plausibility?</p> <p>11 A. Yes.</p> <p>12 Q. And this study specifically</p> <p>13 would be looking at whether talc bodies and</p> <p>14 asbestos bodies are -- provide a plausible</p> <p>15 mechanism of ovarian cancer formation,</p> <p>16 correct?</p> <p>17 A. Not asbestos bodies.</p> <p>18 Asbestos -- asbestos bodies is a --</p> <p>19 ferruginous, yeah.</p> <p>20 Q. I'm sorry. That's a fair</p> <p>21 point. Let me rephrase it.</p> <p>22 A. Okay.</p> <p>23 Q. Talc particles --</p> <p>24 A. Yeah.</p> <p>25 Q. -- in asbestiform asbestos,</p>	<p>1 talc, those provide a plausible mechanism as</p> <p>2 well?</p> <p>3 MR. DONATH: Objection to form.</p> <p>4 MR. HEGARTY: Objection to</p> <p>5 form.</p> <p>6 THE WITNESS: If inflammation</p> <p>7 is of a certain degree, yes.</p> <p>8 QUESTIONS BY MR. BOWDEN:</p> <p>9 Q. And this goes on to attach the</p> <p>10 proposal from Dr. Mossman, right?</p> <p>11 A. It says so, but it's not</p> <p>12 attached here, of course.</p> <p>13 Q. In 2005, the arm of that study</p> <p>14 that actually went through and became</p> <p>15 published was just the mesothelial side of</p> <p>16 it, correct?</p> <p>17 A. Yes, I believe so. Yes.</p> <p>18 Q. And that's because Luzenac,</p> <p>19 2005 and 2006, decided not to fund the study</p> <p>20 in its entirety, right?</p> <p>21 MR. DONATH: Objection to form.</p> <p>22 THE WITNESS: You know --</p> <p>23 QUESTIONS BY MR. BOWDEN:</p> <p>24 Q. And that may not be information</p> <p>25 that you know. I'm just asking you.</p>
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<p>1 right?</p> <p>2 A. Yes.</p> <p>3 Q. And I appreciate that</p> <p>4 clarification.</p> <p>5 A. No, I --</p> <p>6 Q. And the project costs here in</p> <p>7 2005 was estimated at \$75,000.</p> <p>8 Do you see that there?</p> <p>9 A. Yes.</p> <p>10 Q. And so where it's -- if you</p> <p>11 continue on reading here, "While human</p> <p>12 epidemiology is likely to be determinative,</p> <p>13 studies that demonstrate the absence of a</p> <p>14 plausible mechanism will cast doubts on the</p> <p>15 causal associations between exposure to talc</p> <p>16 and cancer."</p> <p>17 Do you see where I'm reading</p> <p>18 from there?</p> <p>19 A. That's what Mark wrote, yes.</p> <p>20 Q. And the inverse of that is also</p> <p>21 true, correct?</p> <p>22 MR. DONATH: Objection to form.</p> <p>23 QUESTIONS BY MR. BOWDEN:</p> <p>24 Q. That studies which demonstrate</p> <p>25 inflammation when provided -- when exposed to</p>	<p>1 A. Yeah, I'm not sure I do. And</p> <p>2 I'm getting a little confused why this is</p> <p>3 coming to the talc section, unless Luzenac</p> <p>4 was wanting them to take over the funding of</p> <p>5 it.</p> <p>6 Q. Well, it's a talc study, right?</p> <p>7 A. Yes.</p> <p>8 Q. I'm going to hand you Exhibit</p> <p>9 Number 36. This is from Linda Loretz to</p> <p>10 undisclosed recipients.</p> <p>11 Do you see that?</p> <p>12 A. Yes.</p> <p>13 MR. BOWDEN: Hold on a second.</p> <p>14 I'm sorry, this is the wrong document.</p> <p>15 I apologize.</p> <p>16 Tell you what, why don't we</p> <p>17 take a break, and I'll get this</p> <p>18 organized, and we'll finish up.</p> <p>19 VIDEOGRAPHER: The time is now</p> <p>20 4:05. Going off the record.</p> <p>21 (Off the record at 4:05 p.m.)</p> <p>22 VIDEOGRAPHER: All right. The</p> <p>23 time is now 4:22. Back on the record.</p> <p>24 (Glenn Exhibit 36 marked for</p> <p>25 identification.)</p>

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<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. All right. When we left off, 3 we just discussed that in 2005, 2006, Luzenac 4 had decided not to fund the epithelial side 5 of the Mossman study, right? 6 A. Yes. 7 Q. Okay. I'm going to hand you 8 what I'll mark as Exhibit Number 37. This 9 will be P1.85. 10 A. 6. 6 is next. 11 Q. All right. So now in 2007, I 12 want you to turn to page -- page 2 of this 13 document. This is April 13, 2007. 14 Do you see where Dr. Mossman is 15 sending Mark Ellis at IMA-North America an 16 e-mail? 17 A. Yes. 18 Q. And it's talking about the talc 19 microarray study in progress, right? 20 A. Correct. 21 Q. It says, "Dear Mark, please 22 find below our progress and suggested 23 protocol for the, quote, mega experiment 24 based on the duplicate surface area 25 measurements on the talc samples which are</p>	<p>1 Q. Right? 2 Rich Zazenski is right above 3 her, right? 4 A. Yes. 5 Q. And that's Luzenac, correct? 6 A. Yes. 7 Q. And in the body of it, it says, 8 "Ladies and gentlemen, please find attached 9 for your consideration a concise experimental 10 plan for the UVM talc research study," right? 11 A. Yes. 12 Q. All of these people on this 13 e-mail are still working together, right? 14 MR. HEGARTY: Objection. Form. 15 THE WITNESS: The ones that you 16 pointed out, yes. 17 QUESTIONS BY MR. BOWDEN: 18 Q. Now, let's go to -- 19 A. When Mr. Ellis makes a 20 transmission like this, he simply sends it to 21 everyone in his talc section, so to speak, 22 the members. 23 Q. Go to page 3 of that document. 24 A. Yes. 25 Q. And so in April of 2007, what</p>
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<p>1 remarkably almost identical to crocidolite 2 asbestos." 3 Do you see that? 4 A. Yes. 5 Q. "Please send it to all our 6 collaborators and sponsors and ask them to 7 get back to Max and me with any concerns, 8 questions or changes. Have a nice weekend." 9 A. Yes. 10 Q. Right? 11 And if you go to the first 12 page -- 13 A. Yes. 14 Q. -- that same day, Mr. Ellis 15 forwards this e-mail on, Dr. Mossman, 16 attaching some of her preliminary results -- 17 A. Yeah. 18 Q. -- with -- he copies -- he 19 sends it to you? 20 A. Yes. 21 Q. Steven Mann, that's Johnson &amp; 22 Johnson, right? 23 A. Yes. 24 Q. Linda Loretz, that's CTFA? 25 A. Right.</p>	<p>1 she's forwarding on to IMA, which is then 2 disseminated to the industry -- 3 A. Yes. 4 Q. -- being Johnson &amp; Johnson -- 5 including Johnson &amp; Johnson and Luzenac -- 6 A. Right. 7 Q. -- is her talc and crocidolite 8 asbestos studies on LP9 mesothelial and IOSE 9 ovarian epithelial cells, right? 10 A. Yes. 11 Q. That's the lung mesothelial and 12 the ovarian cell, right? 13 A. Yes. 14 Q. And it was the mesothelial ones 15 that ultimately were published, correct? 16 That line, correct? 17 MR. HEGARTY: Objection. Form. 18 THE WITNESS: I think -- I 19 guess so, but I need to look at the 20 publication again. 21 (Glenn Exhibit 37 marked for 22 identification.) 23 QUESTIONS BY MR. BOWDEN: 24 Q. Okay. So let's move on to 25 P1.084. Now I'm on Exhibit 37.</p>

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<p>1 A. 85.4? Oh, 37. Okay.</p> <p>2 Q. I'm sorry, sir, it's a little</p> <p>3 confusing.</p> <p>4 A. Okay.</p> <p>5 Q. You see now this is -- starting</p> <p>6 at the second e-mail entry there, this is</p> <p>7 from Dr. Mossman, right?</p> <p>8 A. Uh-huh, yes.</p> <p>9 Q. Sent August --</p> <p>10 A. Yes.</p> <p>11 Q. -- 9, 2007?</p> <p>12 A. Yes.</p> <p>13 Q. Again, she's sending it to Mark</p> <p>14 Ellis, and this time she's copying you --</p> <p>15 A. Yes.</p> <p>16 Q. -- directly on it, right?</p> <p>17 A. Yes, I'm copied.</p> <p>18 Q. Along with Steven Mann?</p> <p>19 A. Yes.</p> <p>20 Q. Linda Loretz?</p> <p>21 A. Right.</p> <p>22 Q. And I think Mr. Zazenski is on</p> <p>23 there as well?</p> <p>24 A. He probably is.</p> <p>25 Q. And it says, "Dear group, I am</p>	<p>1 correct?</p> <p>2 A. It appears.</p> <p>3 Q. Okay. And at the bottom where</p> <p>4 it says "lastly," do you see the bottom</p> <p>5 there?</p> <p>6 A. Yes.</p> <p>7 Q. It says, "Lastly, we are ready</p> <p>8 to run the ovarian epithelial microarrays,"</p> <p>9 right?</p> <p>10 A. Right.</p> <p>11 Q. They haven't even started at</p> <p>12 this point yet. They're just ready to run</p> <p>13 them now --</p> <p>14 A. Yeah.</p> <p>15 Q. -- in August of 2007?</p> <p>16 A. It's what it appears, yes.</p> <p>17 Q. "These cells were less</p> <p>18 sensitive to asbestos by both viability and</p> <p>19 the preliminary microarray experiment, namely</p> <p>20 showing only 54 genes altered after exposure</p> <p>21 to crocidolite asbestos, parentheses, 75, at</p> <p>22 8 hours and only 14 genes changing after</p> <p>23 exposure to crocidolite asbestos, paren, 15,</p> <p>24 at 24 hours."</p> <p>25 What she's talking about is the</p>
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<p>1 attaching the closed table summarizing the</p> <p>2 significant gene changes observed in our</p> <p>3 experience with the LP9 human mesothelial</p> <p>4 cells."</p> <p>5 The significant gene change</p> <p>6 she's talking about are the lungs cells,</p> <p>7 right?</p> <p>8 A. Yes.</p> <p>9 Q. "Note that there were no</p> <p>10 significant changes from no dust control</p> <p>11 groups with either titanium dioxide or glass</p> <p>12 beads and minimal changes with talc."</p> <p>13 Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. "For the paper, gene profiling</p> <p>16 reveals mineral-specific patterns of mRNA</p> <p>17 expression in human mesothelial and human</p> <p>18 ovarian epithelial cells," right?</p> <p>19 A. Yes.</p> <p>20 Q. And then at the bottom -- so</p> <p>21 what's she's talking about there is that she</p> <p>22 has some findings for the lung cells, right?</p> <p>23 A. Uh-huh.</p> <p>24 Q. And she's getting ready to</p> <p>25 publish that paper, at least submit it,</p>	<p>1 number within each of those groups, right?</p> <p>2 That's what the parentheses mean --</p> <p>3 A. Yes.</p> <p>4 Q. -- right?</p> <p>5 And then she goes on and she</p> <p>6 says, "Here is our proposal. Thus we propose</p> <p>7 to have four groups: Control group, zero;</p> <p>8 crocidolite, 75; talc, 75; and titanium</p> <p>9 dioxide, 75," right?</p> <p>10 A. Yes.</p> <p>11 Q. And those control groups are</p> <p>12 going to be tested at both 8 hours and</p> <p>13 24 hours in those experiments, right?</p> <p>14 A. Yes.</p> <p>15 Q. "Any feedback? Sincerely,</p> <p>16 Brooke," right?</p> <p>17 A. Right.</p> <p>18 Q. So her indication at this point</p> <p>19 is that this is what she's going to be doing</p> <p>20 going forward, right?</p> <p>21 A. Uh-huh, yes.</p> <p>22 Q. And so again, this is -- this</p> <p>23 is an update that she's giving not only to</p> <p>24 the IMA-North America, but when she sends</p> <p>25 this out, she's sending it to you, which is</p>



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<p>1 Crowell &amp; Moring, right?</p> <p>2 A. Yes.</p> <p>3 Q. Steven Mann, which is Johnson &amp;</p> <p>4 Johnson?</p> <p>5 MR. HEGARTY: Objection to</p> <p>6 form.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. Correct?</p> <p>9 A. Yes.</p> <p>10 Q. And also to Rich Zazenski, who</p> <p>11 is the person you've been dealing with at</p> <p>12 Rio Tinto, right?</p> <p>13 A. This distribution --</p> <p>14 MR. DONATH: Object to form.</p> <p>15 THE WITNESS: -- would have</p> <p>16 been dictated by Mark Ellis more</p> <p>17 likely than not.</p> <p>18 QUESTIONS BY MR. BOWDEN:</p> <p>19 Q. But this is her e-mail back to</p> <p>20 the entire group, right?</p> <p>21 A. Yes. But I'm saying the</p> <p>22 addressees on the "to" were probably sent to</p> <p>23 her by Mark Ellis. In other words, you know,</p> <p>24 send the e-mail to all of these people.</p> <p>25 Q. Fair enough.</p>	<p>1 It's down in the bottom. It was originally</p> <p>2 published December 2008.</p> <p>3 A. Right. Yeah.</p> <p>4 Q. And it looks like it appeared</p> <p>5 in a volume in 2009.</p> <p>6 A. Yeah.</p> <p>7 Q. At the end of 2008, 2009.</p> <p>8 A. Right. And this is on</p> <p>9 mesothelial cells.</p> <p>10 Q. Right.</p> <p>11 It doesn't have the lung cell</p> <p>12 data?</p> <p>13 A. No, the -- it doesn't have the</p> <p>14 ovarian --</p> <p>15 Q. Ovarian cell data, right.</p> <p>16 Right?</p> <p>17 A. The epidermal cells. That came</p> <p>18 later.</p> <p>19 Q. Okay. Go back to Exhibit</p> <p>20 Number 34.</p> <p>21 A. Yes.</p> <p>22 Q. You go to page 6 in that</p> <p>23 proposal -- or excuse me, in that exhibit,</p> <p>24 you see this is -- she's proposing completing</p> <p>25 that study, the ones we've just been looking</p>
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<p>1 At the top you're going to see</p> <p>2 there's a response from Rich Zazenski.</p> <p>3 Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. And it's a private response,</p> <p>6 Rich Zazenski straight to Dr. Mossman.</p> <p>7 Do you see that there?</p> <p>8 A. Right. Yes.</p> <p>9 Q. And he writes, "Dr. Mossman,</p> <p>10 excellent. You can count on us to provide</p> <p>11 any and all assistance you need."</p> <p>12 Do you see that written?</p> <p>13 A. Yes. Yes.</p> <p>14 (Glenn Exhibit 38 marked for</p> <p>15 identification.)</p> <p>16 QUESTIONS BY MR. BOWDEN:</p> <p>17 Q. Okay. I'm going to show you --</p> <p>18 you had mentioned you wanted to see the</p> <p>19 paper. I'll go ahead and mark that as an</p> <p>20 exhibit, number 38.</p> <p>21 So the paper that she was</p> <p>22 referring to, does this appear to be that</p> <p>23 paper?</p> <p>24 A. What's the date on this?</p> <p>25 Q. It's a little bit hard to see.</p>	<p>1 at?</p> <p>2 A. Yeah, this -- yes, and this was</p> <p>3 a proposal for the human ovarian epithelial</p> <p>4 cells.</p> <p>5 Q. Right.</p> <p>6 A. Right.</p> <p>7 Q. This is the one that was given</p> <p>8 high urgency and high business impact --</p> <p>9 A. Yes.</p> <p>10 Q. -- categorization, right?</p> <p>11 A. Yes.</p> <p>12 MR. DONATH: Objection to form.</p> <p>13 QUESTIONS BY MR. BOWDEN:</p> <p>14 Q. Now -- so go back to the -- to</p> <p>15 the study that we were just looking at. It's</p> <p>16 Exhibit 38.</p> <p>17 A. Yeah, I was just wondering.</p> <p>18 Were these people on this Exhibit 34, they</p> <p>19 addressees on the 37 e-mail? I don't see</p> <p>20 them.</p> <p>21 Q. I'm not following you, sir, but</p> <p>22 I'm trying to -- I just have a couple of</p> <p>23 questions left here.</p> <p>24 A. Well, if this was the -- you</p> <p>25 know, critical from -- from some strategy</p>

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<p style="text-align: right;">Page 418</p> <p>1 point or priority point --</p> <p>2 Q. That's internal to Luzenac.</p> <p>3 A. Yeah, I realize that, but I</p> <p>4 don't see that Wayne Ball and this other guy</p> <p>5 are on this e-mail.</p> <p>6 Q. But Luzenac's on that e-mail,</p> <p>7 right?</p> <p>8 A. Yes.</p> <p>9 Q. Rich Zazenski?</p> <p>10 A. But, I mean, these people are</p> <p>11 saying this is a high priority, but I'm</p> <p>12 surprised if they were that interested. It</p> <p>13 was high priority. They wouldn't be on this</p> <p>14 e-mail about the results.</p> <p>15 But anyway, just a point.</p> <p>16 Q. Okay. So if you go back to --</p> <p>17 A. 37, did you say?</p> <p>18 Q. Yes, sir, the -- 38. 38.</p> <p>19 The study itself, you've got it</p> <p>20 in your right hand, sir.</p> <p>21 A. Oh, this, yeah.</p> <p>22 Q. Yes, sir.</p> <p>23 A. Okay.</p> <p>24 Q. If you turn to the back, you're</p> <p>25 going to see a second to last page of</p>	<p style="text-align: right;">Page 420</p> <p>1 Q. And then they also even give</p> <p>2 acknowledgements to people for performing the</p> <p>3 microarray and realtime quantitative plenary</p> <p>4 chain reaction.</p> <p>5 Do you see that there?</p> <p>6 A. Yes.</p> <p>7 Q. And also for people in helping</p> <p>8 out with the talc characterization.</p> <p>9 Do you see that there?</p> <p>10 A. Yeah, and obtaining of the talc</p> <p>11 samples.</p> <p>12 Q. And this is 2009, right?</p> <p>13 A. That is correct.</p> <p>14 Q. Okay. And in 2009 it was</p> <p>15 appropriate to disclose these conflict of</p> <p>16 interest and the acknowledgements in the way</p> <p>17 they were done.</p> <p>18 Do you feel that?</p> <p>19 MR. DONATH: Objection to form.</p> <p>20 THE WITNESS: She did, yes.</p> <p>21 QUESTIONS BY MR. BOWDEN:</p> <p>22 Q. You feel she did it in an</p> <p>23 appropriate manner?</p> <p>24 A. I think so, yes.</p> <p>25 Q. None of this, these conflict of</p>
<p style="text-align: right;">Page 419</p> <p>1 acknowledgements and conflicts of interest.</p> <p>2 A. Yes.</p> <p>3 Q. Do you see that?</p> <p>4 A. Yes.</p> <p>5 MR. BOWDEN: Pull out both for</p> <p>6 me, please, Corey.</p> <p>7 QUESTIONS BY MR. BOWDEN:</p> <p>8 Q. Do you see the conflict of</p> <p>9 interest statement?</p> <p>10 A. Yes.</p> <p>11 Q. And it says that they received</p> <p>12 support from EUROTALC?</p> <p>13 A. Yes.</p> <p>14 Q. What is EUROTALC?</p> <p>15 A. That's the IMA-Europe talc</p> <p>16 section or talc organization.</p> <p>17 Q. And the Industrial Minerals</p> <p>18 Association for \$90,000 for research?</p> <p>19 A. Yes.</p> <p>20 Q. "None of the authors has a</p> <p>21 financial relationship with a commercial</p> <p>22 entity that has an interest in the subject of</p> <p>23 this manuscript."</p> <p>24 Do you see that there?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 421</p> <p>1 interests or acknowledgements, none of those</p> <p>2 were done by Huncharek and Muscat in the</p> <p>3 Critical Review paper that we covered earlier</p> <p>4 today?</p> <p>5 MR. HEGARTY: Objection.</p> <p>6 MR. DONATH: Objection to form.</p> <p>7 THE WITNESS: I don't think</p> <p>8 they mentioned the amount of money.</p> <p>9 QUESTIONS BY MR. BOWDEN:</p> <p>10 Q. Right. And they didn't --</p> <p>11 A. Huncharek noted the -- noted</p> <p>12 the funding sponsorship by Crowell &amp; Moring.</p> <p>13 Q. Right.</p> <p>14 A. And Huncharek noted</p> <p>15 contribution by -- I forget now, but it might</p> <p>16 have been the talc companies.</p> <p>17 Q. But they didn't notice in the</p> <p>18 Critical Review paper that the funding --</p> <p>19 they said Crowell &amp; Moring.</p> <p>20 A. Yeah.</p> <p>21 Q. They did not note that it came</p> <p>22 from Imerys and Johnson &amp; Johnson, correct?</p> <p>23 MR. HEGARTY: Objection.</p> <p>24 MR. DONATH: Objection to form.</p> <p>25 THE WITNESS: That -- that's --</p>



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<p style="text-align: right;">Page 422</p> <p>1 no, that's correct. 2 QUESTIONS BY MR. BOWDEN: 3 Q. And it would have been 4 appropriate to include that and list it under 5 a subheading called Conflict of Interest 6 Statement? 7 MR. HEGARTY: Objection. Form. 8 MR. DONATH: Objection to form. 9 THE WITNESS: I don't know what 10 that journal required that they 11 publish that paper in. 12 QUESTIONS BY MR. BOWDEN: 13 Q. Okay. So that was the fifth 14 journal they had submitted that paper for 15 publication. 16 You're aware of that, right? 17 MR. HEGARTY: Objection to 18 form. 19 MR. DONATH: Objection to form. 20 THE WITNESS: After you said -- 21 yes, and that often happens when -- 22 QUESTIONS BY MR. BOWDEN: 23 Q. And I'll represent to you -- 24 A. -- journals, you know, don't 25 accept the paper and it goes to another</p>	<p style="text-align: right;">Page 424</p> <p>1 showed me some dates of the impact 2 factor from their publications at that 3 period -- 4 QUESTIONS BY MR. BOWDEN: 5 Q. Sure. 6 A. -- I would have to believe, but 7 I think it was more on the order of a 3, 8 possibly. 9 Q. Could -- 10 A. Occupational safety and health 11 journals and such generally have low impact 12 factors. 13 Q. Right. 14 A. They aren't New England Journal 15 of Medicine or Lancet, so... 16 Q. Do you know whether the 17 journals that rejected that article were 18 higher impact journals? 19 A. I don't know if -- I don't 20 know. 21 Q. So the -- excuse me. If you'll 22 bring back out Exhibit Number 34. P1.76. 23 A. Okay. 24 Q. Go to page 6. 25 A. Yes.</p>
<p style="text-align: right;">Page 423</p> <p>1 journal. 2 Q. Right. 3 A. There's various reasons why 4 they're not -- don't accept them. 5 Q. Okay. And ultimately it was 6 published in the European Journal of Cancer 7 Prevention, right? 8 A. Yes. 9 Q. And you know, do you not, that 10 that's a low impact journal? 11 MR. HEGARTY: Objection to 12 form. 13 MR. DONATH: Objection. 14 THE WITNESS: I'm not sure what 15 the impact factor of that journal is. 16 QUESTIONS BY MR. BOWDEN: 17 Q. You understand that it's about 18 a 1 at the time that they were -- actually 19 had their paper published? 20 MR. HEGARTY: Objection to 21 form. 22 MR. DONATH: Objection to form. 23 THE WITNESS: I didn't know -- 24 I didn't know that, and I question 25 whether it really was a 1. If you</p>	<p style="text-align: right;">Page 425</p> <p>1 Q. "The likelihood of success for 2 this study," which is the ovarian epithelial 3 cell arm of the Mossman study, "is high since 4 this is an extension of the previous Mossman 5 study that demonstrated significant gene 6 changes with talc in human" -- and that 7 should read mesothelial cells -- 8 A. Yes. 9 Q. -- right? 10 MR. DAVANT: Object to form. 11 (Glenn Exhibit 39 marked for 12 identification.) 13 QUESTIONS BY MR. BOWDEN: 14 Q. All right. So then let's move 15 on to what I'm going to mark as Exhibit 16 Number 39. 17 So between 2009 and 2011, are 18 you aware of when the first lawsuit was filed 19 against Luzenac, or what's now Imerys? 20 MR. DONATH: Objection to form. 21 THE WITNESS: I am not. 22 QUESTIONS BY MR. BOWDEN: 23 Q. Okay. Would it surprise you to 24 learn that it was filed in December of 2009? 25 MR. HEGARTY: Objection. Form.</p>

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<p style="text-align: right;">Page 426</p> <p>1 THE WITNESS: It would, yes. 2 QUESTIONS BY MR. BOWDEN: 3 Q. Okay. You hadn't heard that in 4 the 2009, '10, '11 time period that Luzenac, 5 the client that was represented by Crowell &amp; 6 Moring, was beginning to get sued -- 7 MR. DONATH: Objection to form. 8 MR. HEGARTY: Objection to 9 form. 10 QUESTIONS BY MR. BOWDEN: 11 Q. -- by women alleging that 12 exposure to talcum powder had resulted in 13 their ovarian cancer? 14 A. I don't recall that -- 15 MR. DONATH: Objection. 16 THE WITNESS: -- coming from 17 Luzenac. I only recall it vaguely 18 that when I was in my own business, 19 that that's when it started. So I 20 wasn't aware of that. 21 QUESTIONS BY MR. BOWDEN: 22 Q. Okay. And you'd actually gone 23 out from Crowell &amp; Moring in 2010? 24 A. Yes. 25 Q. So what time in 2010 did you</p>	<p style="text-align: right;">Page 428</p> <p>1 following year, your position as a scientific 2 consultant at Crowell &amp; Moring ceases, 3 correct? 4 A. Yes. 5 Q. All right. Do you have 6 Exhibit 39 in front of you now? 7 A. Yes. 8 Q. Okay. Now, I want you to turn 9 to page 3 of that paper, of that exhibit. 10 A. Okay. 11 Q. And you still maintain an 12 e-mail address at Crowell &amp; Moring? 13 A. No, I do not. 14 Q. So -- 15 A. I didn't check e-mail there 16 probably since 2011. 17 Q. Okay. It says, "From Brooke 18 Mossman." It's to John Kelse and to you as 19 well. 20 Do you see that? 21 A. Yes. 22 Q. "Summary of proposed 23 experiments and budget figures. Dear John 24 and Bob, please look this over and see if it 25 makes sense to circulate to your colleagues.</p>
<p style="text-align: right;">Page 427</p> <p>1 leave Crowell &amp; Moring? 2 A. It would have been March. 3 Q. March 2010? 4 A. Yes. 5 Q. Okay. So we were looking just 6 a minute ago at a study proposal that was 7 being summarized internally by Luzenac in 8 September of 2009. That's the one we were 9 just looking at, and you said you didn't 10 recognize some of the names in the paper, 11 right? 12 A. Right. Yes. 13 Q. And then later in 2009, the 14 Byrd complaint is filed? 15 A. The what complaint? 16 MR. DONATH: Objection to form. 17 QUESTIONS BY MR. BOWDEN: 18 Q. The Byrd complaint. It's a -- 19 it was a lawsuit filed against Luzenac. 20 A. Oh, I -- 21 MR. DONATH: Objection. Form. 22 QUESTIONS BY MR. BOWDEN: 23 Q. You weren't aware of that? 24 A. No. 25 Q. Okay. And in March of the</p>	<p style="text-align: right;">Page 429</p> <p>1 Sincerely" -- 2 A. Oh, wait a minute. I was 3 looking at the one above. 4 Q. I've got it up on the screen 5 for you, sir. 6 A. Oh, okay. Yeah. 7 Q. Do you see where it's written? 8 A. Yeah. 9 Q. She's sending it to you in May 10 of 2011, and then -- that was on -- excuse 11 me. That was on May 5th. 12 Do you see where that's 13 written? 14 A. I see May -- yes, May 5th, 15 sent. 16 Q. Okay. Now, go back to page 2, 17 the page before that. 18 A. Okay. 19 Q. You see where John actually 20 responds, right? The bottom of the page? 21 A. Yes. 22 Q. And he's with RT Vanderbilt, 23 right? 24 A. Correct. 25 Q. And he's with IMA-North America</p>



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<p style="text-align: right;">Page 430</p> <p>1 as well?</p> <p>2 A. He's a member of the talc</p> <p>3 section. His company was.</p> <p>4 Q. And he's responding back, and</p> <p>5 he copies you as well, or actually sends it</p> <p>6 to you, right?</p> <p>7 A. Yes.</p> <p>8 Q. And he says, "Sorry for the</p> <p>9 delayed response. I do wish to thank you for</p> <p>10 the revised product description. I</p> <p>11 distributed the revision for further</p> <p>12 discussion and hopefully -- and will</p> <p>13 hopefully have an answer for you shortly."</p> <p>14 Do you see that?</p> <p>15 A. Yes.</p> <p>16 Q. "As earlier mentioned, the</p> <p>17 primary concern now is a legal-oriented worry</p> <p>18 that comparable cellular responses for the</p> <p>19 various assays, greater, lesser, the same, et</p> <p>20 cetera, may be misrepresented by plaintiffs'</p> <p>21 attorneys."</p> <p>22 Right?</p> <p>23 A. Yes.</p> <p>24 Q. People like me?</p> <p>25 A. Yes.</p>	<p style="text-align: right;">Page 432</p> <p>1 form.</p> <p>2 THE WITNESS: Some what</p> <p>3 studies?</p> <p>4 QUESTIONS BY MR. BOWDEN:</p> <p>5 Q. Some of the studies that we've</p> <p>6 talked about. One of the --</p> <p>7 A. The epidemiology studies.</p> <p>8 Q. Yes, sir.</p> <p>9 One of the epidemiology</p> <p>10 studies, right?</p> <p>11 A. Yes.</p> <p>12 Q. "Even though as you state in</p> <p>13 the proposal, dose response studies will be</p> <p>14 employed to determine a dose of crocidolite</p> <p>15 that test positively and a dose of the talcs</p> <p>16 that does not to aid in the control of such a</p> <p>17 like asbestos scenario, this type of like</p> <p>18 asbestos misrepresentation may still remain a</p> <p>19 threat in the legal arena. That's the</p> <p>20 concern at the moment, but we also recognize</p> <p>21 that this concern may be misplaced. We don't</p> <p>22 fully appreciate, understand, the meaning of</p> <p>23 variations likely to be observed. Prior to</p> <p>24 being in the crosshairs of litigation,</p> <p>25 there's little question that by now we would</p>
<p style="text-align: right;">Page 431</p> <p>1 Q. All right. "Basically our</p> <p>2 attorneys believe that demonstrating that a</p> <p>3 test material is not as biologically reactive</p> <p>4 as asbestos can still inappropriately be used</p> <p>5 to argue harm, just to a lesser degree."</p> <p>6 A. Yes, that's what he says.</p> <p>7 Q. "The lesser biological effect,</p> <p>8 if that's what is projected, might be</p> <p>9 described as still a risk for the highly</p> <p>10 susceptible, like the plaintiff, of course."</p> <p>11 Right?</p> <p>12 A. Yes.</p> <p>13 Q. "Obviously risk is not black or</p> <p>14 white. When in the courtroom, any ambiguity</p> <p>15 is sadly used to indict you. That's</p> <p>16 certainly been my take on our legal</p> <p>17 adventures thus far."</p> <p>18 Have I read that correctly?</p> <p>19 A. That's his -- yes.</p> <p>20 Q. Okay. And we've already</p> <p>21 discussed earlier that some of the studies</p> <p>22 were finding statistically significant risk.</p> <p>23 MR. DONATH: Objection to form.</p> <p>24 MR. DAVANT: Objection to form.</p> <p>25 MR. HEGARTY: Objection to</p>	<p style="text-align: right;">Page 433</p> <p>1 have moved ahead with the project."</p> <p>2 Do you see that?</p> <p>3 A. Yes.</p> <p>4 Q. So the only reason they didn't</p> <p>5 move forward with the project to get the</p> <p>6 answer was because they were concerned about</p> <p>7 litigation?</p> <p>8 MR. DONATH: Objection to form.</p> <p>9 QUESTIONS BY MR. BOWDEN:</p> <p>10 Q. That's what this e-mail is</p> <p>11 saying?</p> <p>12 MR. DONATH: Same objection.</p> <p>13 THE WITNESS: That's what it's</p> <p>14 saying from John Kelse, yes.</p> <p>15 QUESTIONS BY MR. BOWDEN:</p> <p>16 Q. When you're talking about women</p> <p>17 who are dying of ovarian cancer, is that a</p> <p>18 reason not to fund the study?</p> <p>19 A. This was --</p> <p>20 MR. DONATH: Objection to form.</p> <p>21 MR. BILLINGS-KANG: Objection</p> <p>22 to form.</p> <p>23 THE WITNESS: I don't believe</p> <p>24 this was a cosmetic talc. I believe</p> <p>25 this was RT Vanderbilt industrial</p>



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<p>1 talc, which really is a misnomer to 2 call it a talc. It is 60 percent 3 non-asbestiform tremolite, 30 percent 4 talc. 5 QUESTIONS BY MR. BOWDEN: 6 Q. And her study was to look at 7 all forms of talc, right? 8 A. I think -- no, I think -- 9 Q. Cosmetic talc, I'm sorry. 10 A. I don't think this study 11 relates to that. I think this study, because 12 John is involved, evidently was of the RT 13 Vanderbilt talc. 14 Q. There's no question that -- 15 A. And he's talking about 16 litigation of RT Vanderbilt. 17 Q. "There's no question this work 18 is meaningful with regard to the broader 19 issue of mechanism." 20 Do you agree with that? 21 MR. HEGARTY: Objection to 22 form. 23 MR. DONATH: Objection to form. 24 THE WITNESS: You know, again, 25 I want to make it clear that I do not</p>	<p>1 meaningful information with regard to the 2 broader issue of mechanism or 3 bioplausibility? 4 MR. HEGARTY: Objection to 5 form. 6 MR. DONATH: Objection to form. 7 THE WITNESS: Cosmetic talc, 8 yes. 9 QUESTIONS BY MR. BOWDEN: 10 Q. Okay. 11 A. I'd proposed such previously. 12 Q. And no one -- no one took you 13 up on that offer, right? 14 MR. HEGARTY: Objection. Form. 15 MR. DONATH: Objection. Form. 16 THE WITNESS: Not until much 17 later. 18 QUESTIONS BY MR. BOWDEN: 19 Q. Okay. "I believe there is 20 still reasonable likelihood that I will 21 receive approval for this work. I did, 22 however, want you to understand why we're 23 experiencing this delay. From your prior 24 comments, I know you understand and 25 appreciate the concerns expressed by our</p>
Page 435	Page 437
<p>1 think this is a cosmetic talc that is 2 being -- is looked at it being used in 3 this experiment. 4 QUESTIONS BY MR. BOWDEN: 5 Q. Would doing a study with 6 cosmetic talc provide a meaningful answer to 7 you? 8 MR. DONATH: Objection. 9 Objection to form, sorry. 10 THE WITNESS: I think it would 11 turn out that way, yes. 12 QUESTIONS BY MR. BOWDEN: 13 Q. And I'm not asking whether -- 14 how you think it would turn out, but would 15 the evidence or the conclusions reached by 16 such a study, would that be important in 17 furthering scientific knowledge? 18 MR. DONATH: Object to form. 19 THE WITNESS: If this is 20 genetic microarray, it would further 21 the knowledge of cosmetic talc. 22 QUESTIONS BY MR. BOWDEN: 23 Q. And it would also -- do you 24 agree if there was such a study done with 25 talc, cosmetic talc, that it would provide</p>	<p>1 legal team. If there are any further 2 insights, advice, that you might share from 3 your experience with regard to these 4 concerns, it would be very much appreciated." 5 Do you see where that's 6 written? 7 A. Yes. 8 Q. So what's essentially happened 9 here is the lawyers shut it down, right? 10 MR. DONATH: Objection to form. 11 MR. HEGARTY: Objection. Form. 12 THE WITNESS: It looks like 13 internally legal counsel decided not 14 to go forward with this. 15 QUESTIONS BY MR. BOWDEN: 16 Q. And you're the only person 17 affiliated with the law firm on this e-mail, 18 right? 19 MR. DAVANT: Objection to form. 20 MR. DONATH: Objection to form. 21 THE WITNESS: Yes. 22 QUESTIONS BY MR. BOWDEN: 23 Q. Now, let's go to the first 24 page. 25 A. All right.</p>

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<p style="text-align: right;">Page 438</p> <p>1 Q. Actually, I'm sorry, go back to 2 the second page. 3 A. Okay. 4 Q. See Dr. Mossman's response on 5 Friday, May 27th? 6 A. Yes. 7 Q. And she writes back that she 8 hopes that she can answer some of the 9 questions, right? 10 A. Right. 11 Q. One of the things that would be 12 important to understand -- 13 A. She -- 14 Q. -- is whether talc just 15 generally causes inflammation, right? 16 A. I think it's -- 17 MR. DONATH: Objection. Form. 18 THE WITNESS: What I was 19 stating before is evidenced in the 20 first sentence, effects of mechanism 21 of action of RTV talc -- 22 QUESTIONS BY MR. BOWDEN: 23 Q. Uh-huh. 24 A. -- which is not a cosmetic 25 talc.</p>	<p style="text-align: right;">Page 440</p> <p>1 ceramics, things like that. 2 Q. Right. 3 The study that would include 4 talc as you describe it, you proposed that 5 study? 6 A. Pardon? 7 Q. A similar study to this -- 8 A. Yes. 9 Q. -- utilizing talc as you define 10 it -- 11 A. Talc, pure talc. Yeah, 12 cosmetic talc -- 13 Q. Fine. Cosmetic talc? 14 A. -- I proposed that, yes. 15 Q. You proposed that while you 16 were an employee at Crowell &amp; Moring, 17 correct? 18 A. Yes, I did. 19 Q. And when you proposed that, 20 Luzenac was one of your clients, or was your 21 client? 22 A. Yes, they were. 23 Q. And ultimately when you made 24 that proposal, that was shot down. They 25 showed no interest, correct?</p>
<p style="text-align: right;">Page 439</p> <p>1 Q. Okay. 2 A. So this study has no relevance 3 to cosmetic talc. 4 Q. Industrial talc and cosmetic 5 talc, how do they differ? 6 A. Well, this talc, as I said, 7 it's not a talc. It should -- it's a 8 misnomer. Sometimes it's called an 9 industrial talc, but it doesn't even compare 10 to some of the industrial talcs that are 11 used. 12 This is a very complex 13 mineralogy in this deposit, and it is 14 composed of only 30 percent talc, magnesium 15 silicate. It has about 60 percent 16 non-asbestiform tremolite, and it then has 17 some chlorite and some other minerals. But 18 it is by no way a pure talc or even what you 19 would consider -- what I would consider a 20 talc. 21 Q. Okay. The study, though -- 22 A. It's sold as a talc, industrial 23 talc, but it has uses in industrial use only. 24 Q. The study that would -- 25 A. Paints -- paints, rubber, some</p>	<p style="text-align: right;">Page 441</p> <p>1 A. I wouldn't say no interest -- 2 MR. DONATH: Objection to form. 3 Direct the witness not to answer to 4 the extent it wades into 5 communications from Luzenac directly 6 to you, or even through Crowell &amp; 7 Moring. 8 QUESTIONS BY MR. BOWDEN: 9 Q. Okay. So that was an idea of 10 yours that you had when you were still in 11 discussions not only with Luzenac and 12 Crowell &amp; Moring but also with Johnson &amp; 13 Johnson, correct? 14 MR. HEGARTY: Objection to 15 form. 16 THE WITNESS: I really didn't 17 have direct communications with 18 Johnson &amp; Johnson. 19 QUESTIONS BY MR. BOWDEN: 20 Q. Okay. Well, we've -- go ahead. 21 A. Luzenac personnel would 22 communicate with Johnson &amp; Johnson. I did 23 not advise them on any science that they 24 should be doing or anything. Luzenac would 25 take those proposals to them.</p>

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<p>1 Q. Okay. Okay. And we've seen in 2 these documents, we were just looking at one 3 a moment ago, where Luzenac internally, in 4 2009, was considering a study, correct? A 5 study, this study, right? 6 MR. DONATH: Objection to form. 7 THE WITNESS: No, not this 8 study. Not this -- not this study 9 that John Kelse is talking about. 10 This is an RT Vanderbilt talc. 11 QUESTIONS BY MR. BOWDEN: 12 Q. I'm not saying -- I'm saying a 13 study -- 14 A. Well, you said "this study," 15 and this is the paper in front of me. 16 Q. Okay. 17 A. All right. 18 Q. Let me rephrase then. 19 A. Good. 20 Q. Luzenac had considered doing a 21 similar study with talc? 22 MR. DONATH: Objection to form. 23 THE WITNESS: With cosmetic 24 talc or pure talc. 25</p>	<p>1 the front of this e-mail. 2 A. Okay. 3 Q. You see at the very top, 4 there's a response from Sharma -- from 5 Mr. Sharma. 6 Do you see that? 7 A. Yes. 8 Q. And it's internal. RTM, that's 9 Luzenac, right? 10 A. Yes. 11 MR. DONATH: Objection to form. 12 QUESTIONS BY MR. BOWDEN: 13 Q. And it says, "John Kelse gave 14 me a copy of the Mossman proposal in DC in 15 late April." 16 Right? 17 A. Yes. 18 Q. "I sent the proposals to" -- 19 I'm going to butcher -- 20 A. Coggiola. 21 Q. -- "Coggiola, Wayne Ball and 22 Jocelyn for their comments," right? 23 A. Yes. 24 Q. And Wayne Ball, that's the same 25 gentleman we saw that in 2009 was summarizing</p>
Page 443	Page 445
<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. Yes? 3 A. Yes, pure talc. 4 Q. And they chose not to do that? 5 A. They did not fund it. 6 Q. Right. 7 And that proposal was a 8 proposal that Crowell &amp; Moring was aware of 9 as well -- 10 MR. DONATH: Objection to form. 11 QUESTIONS BY MR. BOWDEN: 12 Q. -- through you? 13 A. Yes. 14 Q. And it was your opinion at the 15 time, and as you sit here today, that such a 16 study would provide meaningful evidence that 17 would contribute to the scientific knowledge 18 surrounding talc and ovarian cancer? 19 MR. DONATH: Objection to form. 20 THE WITNESS: I expected it 21 would based upon my knowledge of the 22 effect of that talc mineral in other 23 cellular systems and in humans. 24 QUESTIONS BY MR. BOWDEN: 25 Q. I want to -- I want to go to</p>	<p>1 that study, right? 2 MR. DONATH: Objection to form. 3 THE WITNESS: And that's a 4 person I never met. 5 QUESTIONS BY MR. BOWDEN: 6 Q. I'm not asking if you ever met 7 him. I'm asking if that's the same name that 8 we saw on that prior document. 9 A. No, I just wanted to let you 10 know I didn't have any communication with 11 that person. 12 But, yes, that's the same. 13 Q. Okay. "Given the history of 14 the Vanderbilt talc and their decision to 15 exit the market, we jointly decided not to 16 participate in this study." 17 Do you see where that's 18 written? 19 A. Yes. 20 Q. "We do not want our name to be 21 associated with their product, particularly 22 if the results turn out to not be as 23 expected," right? 24 A. Yes. 25 Q. And not only did they not want</p>

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<p style="text-align: right;">Page 446</p> <p>1 their name associated with RT Vanderbilt's 2 product, they also chose not to run the study 3 themselves, correct? 4 MR. DAVANT: Object to form. 5 MR. DONATH: Object to form. 6 THE WITNESS: Again, this is 7 two studies she's speaking about. One 8 evidently is the industrial talc, and 9 the other was the cosmetic talc. 10 QUESTIONS BY MR. BOWDEN: 11 Q. They never ran one with 12 cosmetic talc? 13 MR. DAVANT: Objection to form. 14 MR. DONATH: Objection to form. 15 THE WITNESS: No, they did not 16 fund it. 17 QUESTIONS BY MR. BOWDEN: 18 Q. Okay. Still haven't funded it 19 to this day, to your knowledge? 20 MR. DONATH: Objection to form. 21 THE WITNESS: No, I'm no longer 22 associated with Imerys. I'm not sure 23 what they're doing. 24 QUESTIONS BY MR. BOWDEN: 25 Q. To your knowledge, has anyone</p>	<p style="text-align: right;">Page 448</p> <p>1 asbestos. 2 Q. Okay. And what about for the 3 talc arm of it, the talc group? 4 A. The talc did not show an 5 increase, significant increase, in genetic 6 microarray. 7 Q. So let me be very precise in my 8 questions here because I think that the 9 intention of my question is different than 10 what I think you're understanding it to be. 11 My question to you is: In that 12 study that you're referencing right now -- 13 A. Yes. 14 Q. -- in the talc control -- in 15 the talc group -- 16 A. Yes. 17 Q. -- were there any molecular 18 changes, genetic changes? 19 MR. DONATH: Objection to form. 20 THE WITNESS: I would have to 21 look at the paper again. There's two 22 tables at the back of the paper, and 23 they showed the results at -- she did 24 it using surface area, too. 25 And there are two tables at the</p>
<p style="text-align: right;">Page 447</p> <p>1 conducted that study? 2 A. Yes. Yes. IMA-North America 3 and possibly EUROTALC was -- as we looked at 4 earlier, funded the study. 5 Q. Was it published? 6 A. Yes -- yes, I think it was. 7 Q. What journal was it published 8 in? 9 A. I think it was in a cell 10 biology study. We looked at it earlier, I 11 believe. 12 No, there's another one. You 13 didn't show me that one. That one was only 14 of the mesothelial cells. 15 She published her paper of the 16 mesothelial cells and the ovarian cells. 17 I'll send you a copy. 18 Q. What did it show? 19 A. It showed that pure talc did 20 not respond with a genetic microarray. It 21 would trigger -- it was evidence of 22 triggering cancer. 23 Q. Did it have any genetic 24 mutations at all? 25 A. Yes, the positive control</p>	<p style="text-align: right;">Page 449</p> <p>1 back that are very illustrative, and I 2 can't tell you what they were right 3 now, but that's what I would direct 4 you to. 5 QUESTIONS BY MR. BOWDEN: 6 Q. Okay. And you're saying 7 that -- was there any risk associated with 8 talc at all? 9 A. It -- no, not -- not with 10 the -- with the ovarian epithelial cells or 11 the mesothelial cells. 12 Q. None whatsoever? 13 A. There may have been a response, 14 but it wasn't significant. 15 Q. Okay. And when you say 16 "significant," you're talking about 17 statistical significance? 18 A. No, I'm talking about compared 19 to what Brooke and genetic microarray 20 analysis would consider significant. 21 Q. Okay. 22 A. I wish I had the paper with me. 23 It would enlighten us greatly. 24 Q. Okay. 25 A. But it turned out, as I thought</p>

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<p style="text-align: right;">Page 450</p> <p>1 it might, when I proposed this research way 2 back as earlier as, what, 2005? 3 Q. You proposed this study back in 4 2005? 5 A. It was in that area, yes. 6 Q. Okay. 7 A. It's a talc study looking at 8 mesothelial cells. Brooke actually -- I 9 think Brooke brought it to my attention, but 10 it was -- it was earlier. 11 Q. I want to ask you about the 12 diaphragm study that was published as a 13 result of the contract between Crowell &amp; 14 Moring and the Meta-Analysis Research Group. 15 A. Yes. 16 Q. Okay. The two arms in that 17 are -- tell us about the comparative group 18 and the control group in that. 19 A. I'm sorry, which study was 20 that? 21 Q. The diaphragm study. 22 A. I'm getting -- okay. 23 It wasn't -- that was an 24 observational epidemiology study. 25 Q. The meta-analysis?</p>	<p style="text-align: right;">Page 452</p> <p>1 MR. DONATH: Objection. Form. 2 MR. HEGARTY: Objection. Form. 3 THE WITNESS: Yeah. If. 4 QUESTIONS BY MR. BOWDEN: 5 Q. That's not something that you 6 personally looked at or know of? 7 A. I have not looked at the 8 analyses of -- well, I'm somewhat aware of 9 the analyses of these talcs, and I don't 10 think they've ever been shown -- show -- they 11 may have fibers, they may have talc fibers, 12 but not asbestiform fibers. 13 Q. But you don't know that for a 14 fact, correct? 15 MR. HEGARTY: Objection. Form. 16 THE WITNESS: It comes from 17 geology I've read and geologists I've 18 talked with. 19 MR. BOWDEN: Okay. We'll 20 tender the witness to you guys. 21 VIDEOGRAPHER: The time is now 22 4:59. Going off the record. 23 (Off the record at 4:59 p.m.) 24 VIDEOGRAPHER: Okay. The time 25 is now 5:05. Back on the record.</p>
<p style="text-align: right;">Page 451</p> <p>1 A. Yes. 2 Q. Okay. 3 A. So it just looked at the risk 4 related to females who were using diaphragms 5 for birth control. 6 Q. Okay. 7 A. It wasn't an animal study, so 8 you don't have a control population. 9 Q. Right. 10 And so in the diaphragm study, 11 do you know if there was asbestos 12 contamination in the talc? 13 MR. HEGARTY: Objection to 14 form. 15 MR. DONATH: Object to form. 16 THE WITNESS: No. I mean, the 17 talc was never analyzed from that. It 18 was -- it was talc, talcum powder, 19 that females would -- would dust or 20 use in storage of their diaphragm. 21 QUESTIONS BY MR. BOWDEN: 22 Q. Okay. And in looking at 23 that -- if it turned out that the talc did 24 contain asbestos, would that be problematic? 25 A. If.</p>	<p style="text-align: right;">Page 453</p> <p>1 CROSS-EXAMINATION 2 QUESTIONS BY MR. FERGUSON: 3 Q. Mr. Glenn, good afternoon. 4 A. Good afternoon. 5 Q. My name is Ken Ferguson. I 6 represent Imerys in this matter, along with 7 my colleagues, and I have relatively few 8 questions for you. 9 A. Okay. 10 Q. Let me -- let me go through a 11 couple of things first that I think we may 12 have covered early on but it's been a while. 13 Why don't you go ahead and 14 state your name for the record, please. 15 A. Yes, it's Robert Glenn. 16 Q. And where do you live, 17 Mr. Glenn? 18 A. I live on Seabrook Island, 19 South Carolina. 20 Q. Okay. And how far is that from 21 here? I don't even know. 22 A. It's about -- well, from our 23 mountain house, it's about six hours' drive, 24 but most of it's the last 50 miles. 25 Q. And I think maybe when we were</p>



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<p>1 talking off the record, did you go to 2 Clemson? Is that what you said? 3 A. Yes, I did. 4 Q. All right. And what degrees 5 did you get at Clemson? 6 A. I got a degree in entomology, 7 and I left that behind. 8 Q. All right. I've got some 9 questions for you about some exhibits, so if 10 you -- 11 A. All right. 12 Q. -- would, I'll let you go 13 through and pull up the -- the exhibits. 14 Look for number -- I'm seeing it as 31 and as 15 32, so that's a little tricky. 16 It's 31? All right. 17 A. Yeah. This? 18 Q. Correct. 19 A. Okay. 20 Q. And if you turn over to page -- 21 what's listed 3 of 4. 22 A. Okay. 23 Q. And then looks like a letter to 24 Mark Ellis, president of Industrial Minerals 25 Association of North America, correct?</p>	<p>1 A. Yes, it does. 2 Q. So do you -- have you ever seen 3 a final version of this particular letter to 4 Mr. Ellis? 5 A. I have not. I don't recall 6 ever seeing this letter. 7 Q. So as far as this letter 8 itself, is this the only version you've ever 9 seen? 10 A. This is. 11 Q. And based on your experience in 12 the world for a number of years, do people 13 typically send out draft letters or are 14 they -- typically continue to working on 15 them? 16 A. That would certainly not be 17 customary in business. 18 MR. BOWDEN: Form. 19 QUESTIONS BY MR. FERGUSON: 20 Q. Now, as was discussed with you, 21 this particular letter has to do with 22 Mr. Turner indicating that his company was 23 going to -- to cease funding certain -- a 24 certain study that was being conducted at the 25 University of Vermont, correct?</p>
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<p>1 A. It does. 2 Q. Okay. And counsel asked you 3 about this and asked you about a couple of 4 paragraphs, particularly the paragraph about 5 two-thirds of the way down the page when 6 there was talk about somebody putting it in 7 the vernacular, horse has already left the 8 barn. 9 Do you recall that discussion? 10 A. Yes. 11 Q. Now, looking at this document, 12 this page particularly, do you see where it 13 says the lead in, and it has somebody else's 14 name and has a time in there? 15 A. Yes. 16 Q. That's not normally how you 17 send a letter out, is it? 18 A. No. 19 MR. BOWDEN: Objection. Form. 20 Leading. 21 THE WITNESS: This looks like a 22 draft. 23 QUESTIONS BY MR. FERGUSON: 24 Q. I was going to ask you: Does 25 this appear to be a redline draft?</p>	<p>1 A. That was to be conducted there, 2 yes. 3 Q. Correct. 4 And that was called the Mossman 5 study, at least in the first paragraph of 6 this draft letter, right? 7 A. Yes. 8 Q. Okay. Do you know, in fact, 9 whether or not that study was ever completed 10 by Dr. Mossman and her colleagues at the 11 University of Vermont? 12 A. Yes, it was -- to my knowledge, 13 it was completed and funded by IMA-NA and 14 possibly EUROTALC. I might be wrong about 15 that. 16 Q. Let's take a look at 17 Exhibit 38, please, sir. 18 A. Okay. 19 Q. And Exhibit 38 was also 20 discussed with you, and this appears to be a 21 study that -- with Dr. Mossman as the last 22 author listed, correct? 23 A. Yes. Dr. Mossman probably has 24 300 publications, and she has a very 25 productive group, and she oftentimes lists</p>

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<p style="text-align: right;">Page 458</p> <p>1 herself last.</p> <p>2 Q. And there are a number of her</p> <p>3 colleagues at the University of Vermont in</p> <p>4 different departments and in her department</p> <p>5 that are also listed as coauthors here,</p> <p>6 correct?</p> <p>7 A. Yes.</p> <p>8 Q. Okay. So is this considered to</p> <p>9 be the University of Vermont talc study?</p> <p>10 A. It was a talc study by the</p> <p>11 University of Vermont, but they also have</p> <p>12 done other talc studies.</p> <p>13 Q. Certainly -- and looking at the</p> <p>14 timing of it, the exhibit we just talked</p> <p>15 about, Exhibit 31, was dated July 12 of 2006,</p> <p>16 correct?</p> <p>17 A. Yes.</p> <p>18 Q. And this particular study,</p> <p>19 Exhibit 38, indicates that it was received in</p> <p>20 original form, April 11, 2008 --</p> <p>21 A. Right.</p> <p>22 Q. -- and in final form,</p> <p>23 November 24, 2008, correct?</p> <p>24 A. Yes.</p> <p>25 Q. So the Exhibit 31 that was</p>	<p style="text-align: right;">Page 460</p> <p>1 QUESTIONS BY MR. FERGUSON:</p> <p>2 Q. Okay. And --</p> <p>3 A. I was no longer with IMA-NA</p> <p>4 myself, but Imerys -- I do know that Imerys</p> <p>5 was a member.</p> <p>6 Q. So a study that's being</p> <p>7 supported by the IMA is also being supported</p> <p>8 financially, at least indirectly, through the</p> <p>9 member -- members of the organization,</p> <p>10 correct?</p> <p>11 A. That's correct.</p> <p>12 Q. Let me visit with you a little</p> <p>13 bit about IARC. There was a lot of</p> <p>14 discussion about IARC. And let's talk first</p> <p>15 about the categories.</p> <p>16 There was discussion about 2B?</p> <p>17 A. Uh-huh.</p> <p>18 Q. There are a number of other</p> <p>19 categories that IARC, in its procedure --</p> <p>20 A. Yeah.</p> <p>21 Q. -- can classify agents,</p> <p>22 correct?</p> <p>23 A. That's correct.</p> <p>24 Q. And there are about five.</p> <p>25 There are exactly five of those groups,</p>
<p style="text-align: right;">Page 459</p> <p>1 talking about the ceasing of funding for a</p> <p>2 particular study was a year and a half,</p> <p>3 couple years before this one, correct?</p> <p>4 A. Yes.</p> <p>5 Q. And in fact, I think as you-all</p> <p>6 discussed earlier, if you look on the bottom</p> <p>7 left of the first page of Exhibit 38, it</p> <p>8 says, "This work was supported by NIEHS</p> <p>9 training grant," and then there's a long</p> <p>10 number.</p> <p>11 A. Yes.</p> <p>12 Q. "And a contract from EUROTALC</p> <p>13 and the Industrial Minerals Association of</p> <p>14 North America," correct?</p> <p>15 A. That's correct.</p> <p>16 Q. "And NCI," the National Cancer</p> <p>17 Institute, correct?</p> <p>18 A. Yes. Yes.</p> <p>19 Q. So Imerys, to your knowledge,</p> <p>20 has been a member, was a member at this time,</p> <p>21 of the Industrial Minerals Association,</p> <p>22 correct?</p> <p>23 MR. BOWDEN: Form.</p> <p>24 THE WITNESS: Yes, they were.</p> <p>25</p>	<p style="text-align: right;">Page 461</p> <p>1 correct?</p> <p>2 A. Yes. Yes.</p> <p>3 Q. 1, Group 1, is carcinogenic to</p> <p>4 humans, correct?</p> <p>5 A. Yes.</p> <p>6 And as I mentioned earlier,</p> <p>7 this is just the first step of risk</p> <p>8 identification, of -- is -- of risk</p> <p>9 assessment, the identification step. There</p> <p>10 are four or five other steps that were</p> <p>11 contained in the National Academy of Sciences</p> <p>12 Red Book on the risk assessment.</p> <p>13 Q. But the Group 1, carcinogenic</p> <p>14 to humans --</p> <p>15 A. Yes.</p> <p>16 Q. -- that's IARC saying this is</p> <p>17 carcinogenic, correct?</p> <p>18 A. It's saying it's been</p> <p>19 identified as a human carcinogen.</p> <p>20 Q. And then the next group down is</p> <p>21 Group 2A --</p> <p>22 A. Yes.</p> <p>23 Q. -- which is probably</p> <p>24 carcinogenic, correct?</p> <p>25 A. Yes, correct. And that has</p>



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<p style="text-align: right;">Page 462</p> <p>1 sufficient evidence in -- as -- I can't 2 recall now. It's limited evidence in humans, 3 insufficient evidence in animals. 4 Q. Okay. I might be able to help 5 with you that in just a minute. 6 A. Okay. 7 Q. Okay. Then we got 1, we got 8 2A, then we have Group 2B, correct? 9 A. Group 2B. 10 Q. And Group 2B is possibly 11 carcinogenic to humans, correct? 12 A. That's right. That's right. 13 MR. BOWDEN: Object to form. 14 QUESTIONS BY MR. FERGUSON: 15 Q. Group 3 is called not 16 classifiable as to its carcinogenicity to 17 humans, correct? 18 A. That's right. 19 Q. And then finally Group 4 is 20 probably not carcinogenic to humans? 21 A. Right. 22 Q. And in the monograph that was 23 published in 2010 that was being discussed 24 early -- earlier today, perineal use of talc 25 was classified as a Group 2B --</p>	<p style="text-align: right;">Page 464</p> <p>1 distinction between carcinogens 2A and 2B 2 lies on the fact that the experimental 3 evidence is sufficient for 2A and less than 4 sufficient for 2B carcinogens" -- 5 A. Yes. 6 Q. -- "while for both, human 7 evidence is limited," correct? 8 A. Yes. 9 Q. So for a 2B classification, as 10 you were -- as is attributed to you here, 11 experimental evidence is less than sufficient 12 for 2B, and human evidence is limited, 13 correct? 14 A. Yes. Yes. 15 Q. And it goes on to discuss, 16 again attributed to you, what the limited 17 human evidence means. And what it says is, 18 "A positive association has been observed 19 between exposure to the agent and cancer for 20 which a causal interpretation is considered 21 by the working group to be credible, but 22 chance, bias or confounding could not be 23 ruled out with reasonable confidence," 24 correct? 25 A. Right. Yes. And that also</p>
<p style="text-align: right;">Page 463</p> <p>1 A. Yes. 2 Q. -- meaning possibly 3 carcinogenic to humans, correct? 4 A. Yes. 5 Q. Not carcinogenic, Group 1? 6 A. No. 7 Q. Not probably carcinogenic, 8 Group 2A? 9 A. Right. 10 Q. And could you pull out for me 11 Exhibit 28, which are minutes of a talc 12 section teleconference meeting? 13 A. Okay. I have it. 14 Q. I just bracketed the areas I 15 was going to talk about. 16 A. All right. Page 2 then. 17 Q. Yes, sir, I'm on page 2 of this 18 document. 19 A. All right. Yeah. 20 Q. And you see there's a 21 discussion here in this first full paragraph 22 on this page that talks about you, in fact -- 23 A. Yes. 24 Q. -- and says, "Answering to 25 questions, Bob Glenn recalled that the</p>	<p style="text-align: right;">Page 465</p> <p>1 speaks to the point I made about this is the 2 first step in risk assessment. It's 3 essentially saying, you know, we -- this 4 appears to be or is a carcinogen, this is a 5 probable carcinogen, but it doesn't say 6 anything about the magnitude of the risk or 7 anything like that. 8 Q. And here, a 2B agent, possibly 9 carcinogenic, has limited human evidence and 10 a positive association, but chance, bias or 11 confounding could not be ruled out with 12 reasonable confidence? 13 A. That's right. 14 MR. BOWDEN: Objection to form. 15 QUESTIONS BY MR. FERGUSON: 16 Q. And certainly in classifying an 17 agent as carcinogenic, you would have to rule 18 out chance, bias or confounding? 19 A. You would need to. 20 MR. BOWDEN: Objection to form. 21 THE WITNESS: I mean, those 22 would all be essentially some type of 23 flaws in the published literature that 24 was being considered. 25</p>

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<p>1 QUESTIONS BY MR. FERGUSON: 2 Q. Let's look at Exhibit 29, if we 3 could. 4 A. Okay. Yes. 5 Q. Now, counsel talked to you 6 about some of the -- well, we'd better go to 7 the first part of that. I apologize. 8 This is a Rio Tinto memorandum 9 from a number of people -- to a number of 10 people, excuse me, from a couple of people 11 that discusses IARC strategy and initial 12 communications, correct? 13 A. Yes. 14 Q. And counsel discussed with you 15 some of the objectives and some of the 16 stakeholders, as I recall, and indicated that 17 there was -- well, he didn't read any that 18 had anything to do with consumers, correct? 19 MR. BOWDEN: Form. 20 THE WITNESS: I believe so, 21 yes. 22 QUESTIONS BY MR. FERGUSON: 23 Q. Okay. And let's look under the 24 objectives here, if we can. And it says -- 25 and I believe counsel read some of these, but</p>	<p>1 MR. BOWDEN: Objection to form. 2 QUESTIONS BY MR. FERGUSON: 3 Q. And in these bullet points -- 4 bullet points number 4, did they indicate 5 that they were -- wanted to provide 6 information to customers and consumers? 7 A. They did. 8 Q. And in bullet point 5, did they 9 note that they wanted to work closely with 10 body powder customers to ensure a coordinated 11 approach? 12 A. They did. 13 Q. Let's go, if we may, to 14 Exhibit 22, which was also discussed with 15 you. 16 A. Hold on. 17 Q. Sure. Take your time. 18 A. Okay. Yeah. 19 Q. Now, this was a PowerPoint, and 20 as I recall, you prepared this; is that 21 right? 22 A. Yes, I did. 23 Q. And you prepared this based on 24 your review of the scientific literature, 25 correct?</p>
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<p>1 let me get down to the fourth and fifth 2 bullet points -- 3 A. Yeah, I think he -- 4 Q. -- under objectives. 5 A. I think he went over the second 6 bullet. 7 Q. The fourth bullet point there 8 says, "Provide information to customers and 9 their employees and consumers to ensure the 10 safe handling and use of talc," correct? 11 A. Yes. 12 Q. Okay. And that in this 13 memorandum was one of the immediate 14 objectives. They had immediate objectives 15 and at least one long-term objective, right? 16 A. Yes. 17 Q. Then the next item, the fifth 18 bullet point, says, "Work closely with body 19 powder customers to ensure a coordinated 20 approach," correct? 21 A. Yes. 22 Q. So -- 23 A. Very, very responsible in that 24 they're looking to notify their customers and 25 have interaction with their customers.</p>	<p>1 A. That's correct, on talc, yes. 2 Q. And this was dated back in 3 2006 -- 4 A. Correct. 5 Q. -- at a San Juan, Puerto Rico, 6 meeting, right? 7 A. Yes. 8 Q. Let's go ahead and look at -- 9 there's where I run into trouble with the 10 old -- there's the zoom. Okay. Gotcha. Let 11 me try to zoom out. 12 I pulled out one I put some 13 handwriting on, so that's probably not 14 appropriate, but let's just -- you have this? 15 A. Yeah. 16 Q. In this PowerPoint, you 17 stated -- and this is on page -- 18 A. It's not numbered, 19 unfortunately. 20 Q. It's not numbered? 21 A. Yes. 22 Q. But it's the page that 23 starts -- it is titled "Conclusion, ovarian 24 cancer." 25 A. Okay. Is this it, overall</p>

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<p>1 strength and association?</p> <p>2 MR. DONATH: Conclusion.</p> <p>3 THE WITNESS: Yeah.</p> <p>4 QUESTIONS BY MR. FERGUSON:</p> <p>5 Q. The first bullet point says,</p> <p>6 "Only evidence to support a causal</p> <p>7 interpretation is the overall modest,</p> <p>8 positive association, approximately 1.31."</p> <p>9 A. Let me find this -- that's at</p> <p>10 the very end? Yeah, I've got it.</p> <p>11 Q. You got it?</p> <p>12 A. Yes.</p> <p>13 Q. Okay. Now, on this page there</p> <p>14 are four bullet points, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And the last of these bullet</p> <p>17 points says -- again, you prepared this --</p> <p>18 "Evidence does not indicate that talc is a</p> <p>19 risk factor for ovarian cancer in humans."</p> <p>20 Is that correct?</p> <p>21 A. Yes, that's my conclusion.</p> <p>22 Q. Okay. And based upon your</p> <p>23 comment here and your scientific research,</p> <p>24 does talc cause ovarian cancer?</p> <p>25 A. Not to my opinion, it does not.</p>	<p>1 place somewhere where we are today, in</p> <p>2 Asheville, North Carolina.</p> <p>3 Where else do you have a place?</p> <p>4 A. That's it. I have a lot, if</p> <p>5 you want to buy it.</p> <p>6 Q. I thought you said you had a</p> <p>7 mountain home somewhere.</p> <p>8 A. Yeah, I have a mountain home.</p> <p>9 Q. Where is that located?</p> <p>10 A. That's in Tuckasegee, North</p> <p>11 Carolina.</p> <p>12 Q. Where is that?</p> <p>13 A. It's a garden spot. It's near</p> <p>14 Cashiers, North Carolina, in the high</p> <p>15 mountains west of here.</p> <p>16 Q. I think everyone listening to</p> <p>17 this might need a better reference point.</p> <p>18 A. Okay.</p> <p>19 Q. How far is it from where we are</p> <p>20 today in Asheville, North Carolina?</p> <p>21 A. It's 52 miles, and an hour and</p> <p>22 45 minutes by car.</p> <p>23 Q. Mr. Glenn, you gave us some</p> <p>24 information about your educational</p> <p>25 background.</p>
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<p>1 Q. In your opinion, are talc-based</p> <p>2 body powders safe for consumers to use in the</p> <p>3 perineal area?</p> <p>4 MR. BOWDEN: Objection to form.</p> <p>5 Calls for an expert opinion.</p> <p>6 THE WITNESS: Yes, they are.</p> <p>7 MR. FERGUSON: I think those</p> <p>8 are all the questions I have. Thank</p> <p>9 you for your time, sir.</p> <p>10 THE WITNESS: Thank you.</p> <p>11 MR. FERGUSON: Why don't we go</p> <p>12 off the record.</p> <p>13 VIDEOGRAPHER: The time is</p> <p>14 now --</p> <p>15 CROSS-EXAMINATION</p> <p>16 QUESTIONS BY MR. HEGARTY:</p> <p>17 Q. Mr. Glenn, good afternoon.</p> <p>18 A. Good afternoon.</p> <p>19 Q. My name is Mark Hegarty. I</p> <p>20 represent Johnson &amp; Johnson.</p> <p>21 Have we ever met before today?</p> <p>22 A. No, we've not.</p> <p>23 Q. You told counsel for Imerys</p> <p>24 where you currently live. And I think in</p> <p>25 talking to him, you mentioned you also have a</p>	<p>1 You mentioned that you got a</p> <p>2 degree from Clemson in entomology?</p> <p>3 A. Yes.</p> <p>4 Q. What is that?</p> <p>5 A. I was doing medical entomology,</p> <p>6 bugs, and my first job outside of Clemson was</p> <p>7 I went in the US Army and was in Vietnam</p> <p>8 working on infectious diseases transported by</p> <p>9 vectors such as mosquitos, fleas, in the case</p> <p>10 of plague, things like that.</p> <p>11 Q. Well, thank you for your</p> <p>12 service.</p> <p>13 You also mentioned that you</p> <p>14 attended the University of Minnesota?</p> <p>15 A. Yes, I did.</p> <p>16 Q. And what degree did you get</p> <p>17 from the University of Minnesota?</p> <p>18 A. I got a master of public health</p> <p>19 with concentration in industrial hygiene and</p> <p>20 occupational health.</p> <p>21 Q. With regard to what your</p> <p>22 discipline would be, would you consider</p> <p>23 yourself to be a toxicologist?</p> <p>24 A. No.</p> <p>25 Q. What would you consider</p>

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<p>1 yourself to be?</p> <p>2 A. Industrial hygiene is a science</p> <p>3 that deals with -- excuse me -- recognizing</p> <p>4 hazards in industry, evaluating those</p> <p>5 hazards. So taking measurements and such,</p> <p>6 maybe comparing to the recognized standards</p> <p>7 and implementing controls, recommending</p> <p>8 control measures to protect the worker.</p> <p>9 Q. You mentioned that you're still</p> <p>10 working in that field; is that correct?</p> <p>11 A. I don't do much field work</p> <p>12 anymore of that nature. I'm more involved in</p> <p>13 just research and some expert witnessing.</p> <p>14 Q. I should have asked it in a</p> <p>15 different way.</p> <p>16 You're not retired; you still</p> <p>17 work?</p> <p>18 A. I still work, yes.</p> <p>19 Q. Approximately how many hours a</p> <p>20 week do you work?</p> <p>21 A. Probably 40 to 50.</p> <p>22 Q. Okay. So still almost full</p> <p>23 time?</p> <p>24 A. Yeah, almost.</p> <p>25 Q. You mentioned earlier in the</p>	<p>1 involved in the research.</p> <p>2 Q. Fair enough.</p> <p>3 You told us about a number of</p> <p>4 the places you've worked. We talked about</p> <p>5 NIOSH. You also mentioned working at</p> <p>6 Crowell &amp; Moring for a time and now having</p> <p>7 your own consulting business.</p> <p>8 Regardless of where you worked,</p> <p>9 did you always approach any scientific issue</p> <p>10 as letting the data provide the answer as</p> <p>11 opposed to advocating or working towards some</p> <p>12 result?</p> <p>13 A. Most certainly. I think I</p> <p>14 pointed out this morning that some studies</p> <p>15 that I expected that were going to be</p> <p>16 negative turned out to be positive.</p> <p>17 Q. And put another way, as a</p> <p>18 scientist -- would you consider yourself a</p> <p>19 scientist?</p> <p>20 A. Yes.</p> <p>21 Q. As a scientist, did you always</p> <p>22 commit yourself to reporting what the science</p> <p>23 showed regardless of the outcome?</p> <p>24 MR. BOWDEN: Objection to form.</p> <p>25 THE WITNESS: Yes. Yes.</p>
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<p>1 deposition about a study you're involved with</p> <p>2 that was going to cost in the neighborhood of</p> <p>3 \$750,000; is that right?</p> <p>4 A. Yes.</p> <p>5 Q. Can you tell us a little bit</p> <p>6 about that study, but more importantly what</p> <p>7 the 750,000 is for and what -- and just</p> <p>8 confirm that that's money -- that money is</p> <p>9 not going to you, is it?</p> <p>10 A. No. Let's say the personnel</p> <p>11 cost is a minor part of that. I work with</p> <p>12 some colleagues at the University of Vermont,</p> <p>13 Dr. Pamela Vacek; at West Virginia</p> <p>14 University, Dr. Jack Parker, who is a</p> <p>15 pulmonologist; and at Tulane University,</p> <p>16 Dr. Roy Rando, who is an industrial</p> <p>17 hygienist. So there's personnel costs</p> <p>18 related to that.</p> <p>19 But the major costs come in, if</p> <p>20 you want to know the truth, from a radiology</p> <p>21 study we recently conducted. It comes from</p> <p>22 the radiologist. They read X-rays at 35 to</p> <p>23 \$50 each, and in one study we had them read</p> <p>24 4,000-X-rays, three radiologists. They made</p> <p>25 more than any of the other scientists</p>	<p>1 QUESTIONS BY MR. HEGARTY:</p> <p>2 Q. Did you always do that while</p> <p>3 working at Crowell &amp; Moring?</p> <p>4 MR. BOWDEN: Form.</p> <p>5 THE WITNESS: Yes.</p> <p>6 QUESTIONS BY MR. HEGARTY:</p> <p>7 Q. Did you always do that in</p> <p>8 analyzing any issue relating to the safety of</p> <p>9 talcum powder products?</p> <p>10 MR. BOWDEN: Form. Leading.</p> <p>11 THE WITNESS: Yes, my -- my</p> <p>12 first goal is to represent -- is to do</p> <p>13 work on science that would help</p> <p>14 benefit the worker.</p> <p>15 QUESTIONS BY MR. HEGARTY:</p> <p>16 Q. And also as part of that work,</p> <p>17 you were working on science to make sure that</p> <p>18 consumers were safe --</p> <p>19 A. That's correct.</p> <p>20 Q. -- in their use of talcum</p> <p>21 powder products, correct?</p> <p>22 MR. BOWDEN: Objection to form.</p> <p>23 THE WITNESS: That's correct.</p> <p>24 QUESTIONS BY MR. HEGARTY:</p> <p>25 Q. Now, as to your work on ovarian</p>

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<p>1 cancer and talcum powder products, did you 2 always let the data provide the answer? 3 A. It always did. 4 MR. BOWDEN: Form. 5 THE WITNESS: Yes. 6 QUESTIONS BY MR. HEGARTY: 7 Q. And has that data always 8 showed, as you just told us, that talcum 9 powder products are safe? 10 MR. BOWDEN: Form. Leading. 11 THE WITNESS: In the case of 12 talcum powder, yes. 13 QUESTIONS BY MR. HEGARTY: 14 Q. And has that data always shown 15 that talcum powder products do not cause 16 ovarian cancer? 17 MR. BOWDEN: Objection. 18 Leading. Calls for opinion testimony. 19 THE WITNESS: Yes. 20 QUESTIONS BY MR. HEGARTY: 21 Q. Has that data included 22 epidemiologic data, including several large 23 cohort or forward-looking studies that showed 24 no association between talcum powder use and 25 ovarian cancer?</p>	<p>1 thought I was doing that, but I'm 2 sorry. 3 MR. BOWDEN: I might have 4 misheard you. Thank you. 5 QUESTIONS BY MR. HEGARTY: 6 Q. You just mentioned, Mr. Glenn, 7 recall bias. In a document we just looked at 8 a moment ago commenting on IARC's finding as 9 it relates to talc and its finding of 10 category 2B, it mentioned that with regard to 11 that finding that bias could not be ruled 12 out. 13 Was that referring to what you 14 just mentioned, recall bias? 15 A. Yes, it was. You know, in most 16 studies -- and also there's an exposure part 17 that has some methodological issues, and that 18 is how you quantify exposure from perineal 19 application of talc. 20 Q. We talked about the 21 epidemiologic data and how the cohort studies 22 and even the -- many of the case-control 23 studies do not show a link or causation 24 between talcum powder use and ovarian cancer? 25 A. Yeah.</p>
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<p>1 MR. BOWDEN: Form. 2 THE WITNESS: There were -- 3 there was one prospective study that 4 was mentioned this morning, that's the 5 Gertig study, and that's the one that 6 has less methodological problems for 7 many reasons. One is because it did 8 not -- you did not have to rely on a 9 recall bias of when you -- how much or 10 when you used talcum. That was 11 answered up front by the nurses in the 12 study. 13 Secondly, it showed -- it 14 failed to show an exposure/response 15 relationship between the use of talcum 16 powder and ovarian cancer. 17 MR. BOWDEN: Counsel, I just 18 want to interject real quickly. I'm 19 stating some objections. I know I'm 20 not sitting right across from you 21 right now. If you'll let me state my 22 objection cleanly for the record and 23 then give your response, I would 24 appreciate it. 25 THE WITNESS: I will. I</p>	<p>1 MR. BOWDEN: Objection. Form. 2 QUESTIONS BY MR. HEGARTY: 3 Q. But as also the animal studies 4 that were done show that talcum powder does 5 not cause ovarian cancer? 6 MR. BOWDEN: Form. 7 THE WITNESS: As I mentioned 8 this morning, the studies that IARC 9 considered to be most informative in 10 answering that question of is talc -- 11 talcum powder increase risk of ovarian 12 cancers, two did, two were more or 13 less, and then uninterpretable, if you 14 will, three were negative, and then 15 the cohort study of Gertig, which I 16 consider to be the strongest, did not 17 find a positive relationship to dose. 18 MR. BOWDEN: Objection. Form. 19 Opinion. 20 QUESTIONS BY MR. HEGARTY: 21 Q. Has the data showing that 22 talcum powder products do not cause ovarian 23 cancer also include cell studies? 24 A. Yes, they have. There are 25 some.</p>

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<p>1 Q. And have the studies that have 2 been done shown that talcum powder is not 3 genotoxic, meaning that it doesn't damage the 4 genes?</p> <p>5 MR. BOWDEN: Objection. Form. 6 THE WITNESS: It is -- it has 7 shown that it does not respond with 8 genetic changes that would indicate 9 that it's triggering a mechanism of 10 cancer, yes.</p> <p>11 QUESTIONS BY MR. HEGARTY: 12 Q. Has the data also showed that 13 talcum powder is not cytotoxic, meaning it 14 doesn't damage cells?</p> <p>15 MR. BOWDEN: Objection. Form. 16 THE WITNESS: Yes.</p> <p>17 QUESTIONS BY MR. HEGARTY: 18 Q. And has the data also showed 19 that talcum powder is not mutagenic, meaning 20 it doesn't mutate genes?</p> <p>21 A. Yes. 22 Q. And when you talk about the 23 studies on talcum powder, what has been 24 studied are the powders that women use on 25 their bodies in the perineal area.</p>	<p>1 identification.)</p> <p>2 QUESTIONS BY MR. HEGARTY: 3 Q. And I'm going to mark as 4 Exhibit 40 -- I think that's the exhibit 5 we're on. 6 A. Yeah. 7 Q. Exhibit 40 is a February 28, 8 2005 document signed by Ridgway Hall going to 9 Drs. Huncharek and Muscat. 10 First of all, are you familiar 11 with this document? 12 A. I have seen this document, yes. 13 Q. Is this a document that counsel 14 for plaintiffs showed you? 15 A. No, I didn't see this from 16 plaintiffs. 17 Q. Would you turn over to about 18 page 4 of the -- of Exhibit 40, which refers 19 to attachment A at the top? 20 A. Oh, yes. Yeah. 21 Q. Is this an attachment you're 22 familiar with, Mr. Glenn? In other words, 23 have you seen it before right now? 24 A. I've seen this before, yes. 25 Q. This, in the end, was the</p>
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<p>1 A. Right. 2 Q. Regardless of what's in them, 3 whether it includes asbestiform fibers, as 4 the plaintiffs have contended, or not, that's 5 the product that's been studied that has not 6 been shown to be cytotoxic, genotoxic, 7 mutagenic, and shown to be safe, correct?</p> <p>8 A. Yes. 9 MR. BOWDEN: Objection to form. 10 QUESTIONS BY MR. HEGARTY: 11 Q. You were asked a number of 12 questions by counsel for plaintiffs regarding 13 your work with Crowell &amp; Moring and the 14 studies authored by Drs. Muscat and Huncharek 15 that were published in 2007 and 2008. 16 Do you recall those questions? 17 A. Yes. 18 Q. I want to talk about those 19 studies. In particular, I want to make sure 20 of the chronology and facts of those studies. 21 I first want to show you a 22 document that was not provided to you by 23 plaintiff's counsel. 24 MR. BOWDEN: Objection. Form. 25 (Glenn Exhibit 40 marked for</p>	<p>1 retainer agreement that was entered into 2 between Drs. Huncharek and Muscat and 3 Crowell &amp; Moring, correct?</p> <p>4 A. Yes, it was. 5 Q. If we look at the retainer 6 agreement, the work that was being requested 7 by Crowell &amp; Moring were two papers that 8 could be called white papers -- 9 A. Yes. 10 Q. -- that were to be potentially, 11 in the end, submitted to NTP as part of the 12 2004 ROC process, correct? 13 A. Yes. 14 Q. Those two papers were to be a 15 review of the existing literature looking at 16 talc use and ovarian cancer, and an analysis 17 of the risk of ovarian cancer in users of 18 talc-dusted diaphragms, correct? 19 A. Yes. 20 Q. And would it be a correct 21 statement that you and Crowell &amp; Moring 22 expected Drs. Huncharek and Muscat to 23 approach this work as independent scientists, 24 where their analysis and results be based 25 solely on the data and not on what you</p>

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<p>1 thought anyone wanted to hear?</p> <p>2 MR. BOWDEN: Objection to form.</p> <p>3 THE WITNESS: It was. It was</p> <p>4 their independent research we were</p> <p>5 looking for.</p> <p>6 QUESTIONS BY MR. HEGARTY:</p> <p>7 Q. And from your standpoint, did</p> <p>8 Drs. Huncharek and Muscat do just that with</p> <p>9 regard to the work they did on the diaphragm</p> <p>10 and Critical Review paper?</p> <p>11 MR. BOWDEN: Objection. Form.</p> <p>12 THE WITNESS: Yes, they did.</p> <p>13 QUESTIONS BY MR. HEGARTY:</p> <p>14 Q. And as to any work you did in</p> <p>15 connection with preparing these white papers,</p> <p>16 any involvement that you had, did you</p> <p>17 approach this work as you have always</p> <p>18 approached scientific issues? You would</p> <p>19 analyze the data as it is and draw</p> <p>20 conclusions from the data without regard to</p> <p>21 the final results?</p> <p>22 MR. BOWDEN: Objection to form.</p> <p>23 THE WITNESS: Yes.</p> <p>24 QUESTIONS BY MR. HEGARTY:</p> <p>25 Q. And under the contract, did it</p>	<p>1 A. No, there was not.</p> <p>2 Now that you mention that, I</p> <p>3 think there was some communication that J&amp;J</p> <p>4 was shown -- was on the paperwork, so</p> <p>5 obviously they knew that J&amp;J and Imerys were</p> <p>6 involved in the funding.</p> <p>7 Q. In fact, I think you mentioned</p> <p>8 this earlier. The 2000 -- did the authors,</p> <p>9 Drs. Huncharek and Muscat, acknowledge the</p> <p>10 finding of Johnson &amp; Johnson and Imerys in</p> <p>11 the 2007 paper on diaphragm use?</p> <p>12 A. Yes, they did.</p> <p>13 Q. If we look at the agreement</p> <p>14 that we marked as Exhibit Number 40, at the</p> <p>15 bottom, do you see where it talks about the</p> <p>16 second project included a meta-analysis</p> <p>17 examining the possible association of</p> <p>18 cosmetic talc with contraceptive diaphragms</p> <p>19 and the risk of cancer of the ovary?</p> <p>20 Do you see that?</p> <p>21 A. Yes. Yes.</p> <p>22 Q. And then if we look at the last</p> <p>23 paragraph, it refers to potential work to</p> <p>24 reformat that paper to make it suitable for</p> <p>25 publication.</p>
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<p>1 specify that the review paper, as mentioned,</p> <p>2 and the diaphragm paper was potentially going</p> <p>3 to be submitted to the NTP, but did you</p> <p>4 understand, though, that they were never</p> <p>5 submitted?</p> <p>6 A. Yes, I do.</p> <p>7 Q. Now, you were also asked about</p> <p>8 the funding provided to support the</p> <p>9 preparation of the two white papers that may</p> <p>10 be going potentially to the NTP.</p> <p>11 Do you recall those questions?</p> <p>12 A. Yes.</p> <p>13 Q. Do you know whether J&amp;J or</p> <p>14 Imerys knew back then that -- of whether the</p> <p>15 payment information was passed along to</p> <p>16 Drs. Huncharek and Muscat?</p> <p>17 MR. BOWDEN: Objection.</p> <p>18 THE WITNESS: That was in</p> <p>19 Ridge, Ridge Hall's, involvement, and</p> <p>20 so I'm not sure I did on that.</p> <p>21 QUESTIONS BY MR. HEGARTY:</p> <p>22 Q. Do you know whether there was</p> <p>23 an effort to keep Drs. Huncharek and Muscat</p> <p>24 in the dark about the funding sources for</p> <p>25 those white papers?</p>	<p>1 A. Yes.</p> <p>2 Q. But if we look above, we see</p> <p>3 where it talks about the first project being</p> <p>4 the Critical Review paper, correct?</p> <p>5 A. Yes.</p> <p>6 Q. Do you see in the middle, the</p> <p>7 paragraph that talks about publishing the</p> <p>8 Critical Review paper was actually crossed</p> <p>9 out?</p> <p>10 A. Yes.</p> <p>11 Q. So from this contract, there</p> <p>12 was no plans to publish the Critical Review</p> <p>13 white paper, correct?</p> <p>14 A. Not here, no.</p> <p>15 Q. So anyone reading this</p> <p>16 contract, including J&amp;J, would see that it</p> <p>17 specified that there would be an effort to</p> <p>18 publish the diaphragm study but not the</p> <p>19 Critical Review paper, correct?</p> <p>20 A. That's what it, yes, appears</p> <p>21 to --</p> <p>22 MR. BOWDEN: Objection.</p> <p>23 QUESTIONS BY MR. HEGARTY:</p> <p>24 Q. Indeed was the diaphragm study</p> <p>25 published in 2007?</p>

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<p>1 A. Yes, it was.</p> <p>2 Q. Would that study have gone</p> <p>3 through the peer-review process?</p> <p>4 A. It would have gone through the</p> <p>5 journal's process, yes.</p> <p>6 Q. And have you had a chance to</p> <p>7 review that article?</p> <p>8 A. I've reviewed the article, yes.</p> <p>9 Q. Okay. From your standpoint,</p> <p>10 was the data reported accurate?</p> <p>11 A. Yes, it was.</p> <p>12 Q. Are you aware of anyone in the</p> <p>13 scientific community identifying any</p> <p>14 inaccuracies in the data or their</p> <p>15 conclusions?</p> <p>16 MR. BOWDEN: Objection.</p> <p>17 THE WITNESS: I don't recall</p> <p>18 any letters to the editor objecting to</p> <p>19 anything in that paper.</p> <p>20 QUESTIONS BY MR. HEGARTY:</p> <p>21 Q. Did that data show that there</p> <p>22 was no causal connection between use of</p> <p>23 talc-dusted diaphragms and ovarian cancer?</p> <p>24 A. Yes.</p> <p>25 MR. BOWDEN: Objection.</p>	<p>1 were copied on, but I had very little contact</p> <p>2 with Dr. Mann or anyone at J&amp;J.</p> <p>3 Q. From your standpoint, did</p> <p>4 Johnson &amp; Johnson have any involvement in the</p> <p>5 results or final wording of the published</p> <p>6 diaphragm study?</p> <p>7 MR. BOWDEN: Objection. Form.</p> <p>8 THE WITNESS: No, they did not.</p> <p>9 QUESTIONS BY MR. HEGARTY:</p> <p>10 Q. I want to next talk about the</p> <p>11 white paper for the Critical Review.</p> <p>12 Just focusing on the white</p> <p>13 paper first --</p> <p>14 A. Yes.</p> <p>15 Q. -- to your knowledge, did J&amp;J</p> <p>16 have any involvement in the preparation of</p> <p>17 the Critical Review white paper?</p> <p>18 MR. BOWDEN: Objection. Form.</p> <p>19 THE WITNESS: No.</p> <p>20 QUESTIONS BY MR. HEGARTY:</p> <p>21 Q. Have you been shown anything</p> <p>22 showing that Johnson &amp; Johnson suggested any</p> <p>23 changes to the Critical Review white paper?</p> <p>24 MR. BOWDEN: Form.</p> <p>25 THE WITNESS: No.</p>
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<p>1 QUESTIONS BY MR. HEGARTY:</p> <p>2 Q. And has there been other</p> <p>3 studies that have been -- that have looked at</p> <p>4 and rated talc-dusted diaphragms users and</p> <p>5 ovarian cancer came to the same conclusion?</p> <p>6 A. I don't recall any, but</p> <p>7 Dr. Huncharek was interested in following</p> <p>8 that up in a study.</p> <p>9 Q. With regard to the diaphragm</p> <p>10 study, to your knowledge -- or do you have</p> <p>11 any knowledge of J&amp;J, or Johnson &amp; Johnson,</p> <p>12 making any suggested revisions to that paper?</p> <p>13 A. No.</p> <p>14 Q. Are you aware of Johnson &amp;</p> <p>15 Johnson requesting or requiring any changes</p> <p>16 be made?</p> <p>17 A. No.</p> <p>18 MR. BOWDEN: Objection. Form.</p> <p>19 QUESTIONS BY MR. HEGARTY:</p> <p>20 Q. Did you have any communications</p> <p>21 at all with Johnson &amp; Johnson about the</p> <p>22 diaphragm white paper or the diaphragm study?</p> <p>23 A. As I mentioned, I really had</p> <p>24 limited communications with J&amp;J, most of</p> <p>25 those things where I was copied on or they</p>	<p>1 QUESTIONS BY MR. HEGARTY:</p> <p>2 Q. Have you seen anywhere that</p> <p>3 Johnson &amp; Johnson requested, requiring --</p> <p>4 required any changes to the white paper on</p> <p>5 the critical review?</p> <p>6 MR. BOWDEN: Form.</p> <p>7 THE WITNESS: No.</p> <p>8 QUESTIONS BY MR. HEGARTY:</p> <p>9 Q. Now, after that white paper was</p> <p>10 finished -- and by the way, do you</p> <p>11 remember -- do you recall when the two white</p> <p>12 papers were completed, what time frame?</p> <p>13 A. Sitting here right now, no.</p> <p>14 I'd have to look back through some of the</p> <p>15 papers.</p> <p>16 Q. Do you recall that the drafts</p> <p>17 were actually completed in 2005?</p> <p>18 MR. BOWDEN: Form.</p> <p>19 THE WITNESS: That may have</p> <p>20 been, yes.</p> <p>21 QUESTIONS BY MR. HEGARTY:</p> <p>22 Q. Do you recall in particular</p> <p>23 that the drafts were completed before the</p> <p>24 IARC proceedings in 2006?</p> <p>25 MR. BOWDEN: Form.</p>

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<p>1 THE WITNESS: Yes, I remember 2 now, in one of Ridge's letters I 3 looked at earlier, he stated dates, 4 target dates, that we would like to 5 see the papers, yes. 6 QUESTIONS BY MR. HEGARTY: 7 Q. Those target dates were in 8 2005? 9 A. Yes. 10 Q. Now, after the white paper was 11 finished, do you understand that 12 Drs. Huncharek and Muscat, without any 13 involvement from Imerys and J&amp;J, created a 14 new Critical Review white paper that they -- 15 ultimately was published in the European 16 Journal of Cancer Epidemiology? 17 MR. BOWDEN: Objection to form. 18 THE WITNESS: Yes. 19 QUESTIONS BY MR. HEGARTY: 20 Q. To your knowledge, was Johnson 21 &amp; Johnson even aware that Drs. Muscat and 22 Huncharek were trying to publish the Critical 23 Review white paper in the European Journal of 24 Cancer Epidemiology? 25 MR. BOWDEN: Objection to form.</p>	<p>1 at Exhibit Number 18, the published Critical 2 Review white paper, being shown Exhibit 3 Number 17, which was the white paper that had 4 comments included in the white paper? 5 Do you recall that larger 6 document? 7 A. Yes, I do. 8 Q. And have you had a chance to do 9 a side-by-side comparison between the white 10 paper that was generated under the contract 11 with Crowell &amp; Moring and the published 12 paper, Exhibit Number 18, that eventually 13 made its way into the public domain? 14 A. I have not done a side-by-side. 15 I've read the paper. I think the paper is a 16 good paper. 17 Q. Plaintiff's counsel showed you 18 the disclosure that Drs. Muscat and Huncharek 19 made as part of this paper. 20 First of all, is it correct 21 that the lead author is responsible for doing 22 the acknowledgements or the disclosure in a 23 paper? 24 A. It's -- it could be a combined, 25 but usually the lead author is certainly the</p>
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<p>1 THE WITNESS: I don't think 2 they were aware of it. 3 QUESTIONS BY MR. HEGARTY: 4 Q. So would it be correct to say 5 that you're not aware of Johnson &amp; Johnson 6 having any involvement whatsoever in the 7 content of the Critical Review article that 8 was published? 9 MR. BOWDEN: Form. 10 THE WITNESS: That's correct. 11 QUESTIONS BY MR. HEGARTY: 12 Q. Now, are you aware of any 13 communications by Drs. Huncharek and Muscat 14 with Johnson &amp; Johnson about the published 15 Critical Review paper? 16 A. I am not. 17 Q. You were shown the published 18 Critical Review paper. Do you happen to have 19 that paper in front of you, Doctor? I think 20 it was marked as an exhibit. 21 MR. DONATH: 18. 22 MR. HEGARTY: Exhibit 18. 23 THE WITNESS: Boy, you're good. 24 QUESTIONS BY MR. HEGARTY: 25 Q. Do you recall prior to looking</p>	<p>1 one that has correspondence back and forth 2 with the journal editor and is the one 3 responsible that they follow the guidelines 4 for a manuscript. 5 Q. I think you mentioned earlier 6 you did not have a chance to read 7 Dr. Muscat's testimony about why he worded 8 the acknowledgement section as he did; is 9 that correct? 10 A. I have not seen that. 11 Q. And counsel for plaintiffs did 12 not show you Dr. Muscat's testimony about why 13 he worded the acknowledgement the way he did, 14 correct? 15 MR. BOWDEN: Objection. Form. 16 THE WITNESS: No counsel didn't 17 show me his testimony. 18 QUESTIONS BY MR. HEGARTY: 19 Q. As far as the best source of 20 why the acknowledgement was worded as it was, 21 would that be either Dr. Muscat or 22 Dr. Huncharek? 23 MR. BOWDEN: Objection. Form. 24 THE WITNESS: Yes, they would 25 have been responsible for that.</p>

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<p>1 QUESTIONS BY MR. HEGARTY:</p> <p>2 Q. Did you have any communication</p> <p>3 with them at all about the preparation of the</p> <p>4 acknowledgement section in this published</p> <p>5 paper?</p> <p>6 A. No.</p> <p>7 Q. And have you -- did plaintiff's</p> <p>8 counsel show you Dr. Muscat's testimony from</p> <p>9 his deposition where he said that he wrote</p> <p>10 this article, Exhibit 18, as a new article,</p> <p>11 independent of the Critical Review white</p> <p>12 paper? Have you seen that testimony?</p> <p>13 MR. BOWDEN: Objection to form.</p> <p>14 THE WITNESS: I have not seen</p> <p>15 that.</p> <p>16 QUESTIONS BY MR. HEGARTY:</p> <p>17 Q. And did plaintiff's counsel</p> <p>18 show you Dr. Muscat's testimony where he said</p> <p>19 that the funds for the article that was</p> <p>20 published did not come from the original</p> <p>21 Crowell &amp; Moring contract but from the NIH</p> <p>22 grant that he references in this</p> <p>23 acknowledgement? Did they show you that</p> <p>24 testimony?</p> <p>25 MR. BOWDEN: Objection to form.</p>	<p>1 Foundation and Dr. Wynder, and he published a</p> <p>2 lot about cigarette smoking with Dr. Wynder.</p> <p>3 MR. BOWDEN: Form.</p> <p>4 THE WITNESS: Surely that would</p> <p>5 give me confidence that he was a</p> <p>6 credible researcher.</p> <p>7 QUESTIONS BY MR. HEGARTY:</p> <p>8 Q. And with regard to the</p> <p>9 preparation of the Critical Review white</p> <p>10 paper and its relationship to the -- I'm</p> <p>11 sorry, let me start over again.</p> <p>12 With regard to the preparation</p> <p>13 of the Critical Review paper that was</p> <p>14 published in relationship to the Critical</p> <p>15 Review white paper, would you defer to</p> <p>16 Dr. Muscat as far as what was done between</p> <p>17 the two papers?</p> <p>18 A. Yes. Certainly. I don't think</p> <p>19 we commented at all on any of the manuscripts</p> <p>20 they submitted. It was only on the reports.</p> <p>21 Q. So would it be a correct</p> <p>22 statement that you never provided comments on</p> <p>23 the actual manuscripts that were being</p> <p>24 submitted to the journals for their</p> <p>25 consideration?</p>
Page 499	Page 501
<p>1 THE WITNESS: They did not show</p> <p>2 me that.</p> <p>3 QUESTIONS BY MR. HEGARTY:</p> <p>4 Q. Are you aware that Dr. Muscat</p> <p>5 still considers this disclosure to be a</p> <p>6 proper disclosure for this review paper?</p> <p>7 MR. BOWDEN: Form.</p> <p>8 THE WITNESS: I've not had any</p> <p>9 communication with Dr. Muscat</p> <p>10 regarding that question.</p> <p>11 QUESTIONS BY MR. BOWDEN:</p> <p>12 Q. In your dealings with</p> <p>13 Dr. Muscat, did you find him to be a highly</p> <p>14 qualified scientist?</p> <p>15 MR. BOWDEN: Form.</p> <p>16 THE WITNESS: Yes, I did.</p> <p>17 QUESTIONS BY MR. HEGARTY:</p> <p>18 Q. Did you respect him as a</p> <p>19 scientist?</p> <p>20 A. Yes, I did.</p> <p>21 He had worked at the American</p> <p>22 Health Foundation with Dr. Ernst Wynder, who</p> <p>23 was responsible mainly for linking cigarette</p> <p>24 smoking to lung cancer. And they had</p> <p>25 impeccable credentials, the American Health</p>	<p>1 A. That's correct.</p> <p>2 MR. BOWDEN: Objection to form.</p> <p>3 QUESTIONS BY MR. HEGARTY:</p> <p>4 Q. You mentioned even earlier</p> <p>5 that -- in response to plaintiff's counsel</p> <p>6 question, and I think you were cut off --</p> <p>7 that it would be improper to reference you in</p> <p>8 the published Critical Review paper.</p> <p>9 Do you recall wanting to make</p> <p>10 that statement?</p> <p>11 A. Yes.</p> <p>12 Q. Can you tell us why it would be</p> <p>13 improper for you to have been listed there?</p> <p>14 A. Journals have gotten much more</p> <p>15 stringent in the last ten years or so about</p> <p>16 who is an author and who is not an author,</p> <p>17 and you pretty much have to assert and</p> <p>18 essentially have some strong support that the</p> <p>19 person contributed in a meaningful way.</p> <p>20 Example, the two papers that</p> <p>21 we've just published on industrial sand. On</p> <p>22 the medical portion of the paper, the medical</p> <p>23 paper, the epidemiology, because the</p> <p>24 radiologist read the X-rays, we included him.</p> <p>25 On the dust exposure part --</p>

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<p>1 paper that was submitted, they were not</p> <p>2 included because they didn't have anything to</p> <p>3 do with dust exposure.</p> <p>4 So you -- now they're wanting</p> <p>5 you to be -- they want to be assured that the</p> <p>6 authors really had something to do with the</p> <p>7 paper.</p> <p>8 Sometimes in the past it was a</p> <p>9 research group, would list a lot of names,</p> <p>10 just -- that's changed.</p> <p>11 Q. So would it be improper for</p> <p>12 Drs. Huncharek and Muscat to have listed you</p> <p>13 on either of the papers, the diaphragm study</p> <p>14 or the Critical Review study?</p> <p>15 MR. BOWDEN: Objection. Form.</p> <p>16 THE WITNESS: If I had known</p> <p>17 about it, I wouldn't have let them</p> <p>18 list me on the paper.</p> <p>19 QUESTIONS BY MR. HEGARTY:</p> <p>20 Q. Would it be proper for anyone</p> <p>21 to argue that the diaphragm study and the</p> <p>22 Critical Review study were written so that</p> <p>23 Johnson &amp; Johnson or Imerys could try to</p> <p>24 influence scientists or regulators as to the</p> <p>25 safety of talcum powder products?</p>	<p>1 IARC did that in what they said about</p> <p>2 those most informative studies.</p> <p>3 The weight of the evidence</p> <p>4 seemed to be that it was not a</p> <p>5 relationship.</p> <p>6 QUESTIONS BY MR. HEGARTY:</p> <p>7 Q. You were also asked a little</p> <p>8 bit about providing comments on the white</p> <p>9 papers.</p> <p>10 Is there anything wrong with --</p> <p>11 in the context of an author working on a</p> <p>12 white paper and showing it to others, with</p> <p>13 others providing comments with regard to</p> <p>14 grammar, wording, making sure that the -- the</p> <p>15 paper was easily understandable? Is there</p> <p>16 anything wrong with that?</p> <p>17 A. No, and I'd go a little further</p> <p>18 than that. If something is left out that</p> <p>19 would add to the paper and the author knew --</p> <p>20 and it was brought to the author's attention,</p> <p>21 they may want to put that in.</p> <p>22 Q. In your experience, has such a</p> <p>23 process been helpful in making sure the paper</p> <p>24 properly communicates the information and to</p> <p>25 identify any unforeseen problems in the way</p>
Page 503	Page 505
<p>1 MR. BOWDEN: Objection to form.</p> <p>2 THE WITNESS: No, it wouldn't.</p> <p>3 No, it was not that way.</p> <p>4 QUESTIONS BY MR. HEGARTY:</p> <p>5 Q. Would that be an improper</p> <p>6 argument to make?</p> <p>7 A. Yeah.</p> <p>8 MR. BOWDEN: Objection.</p> <p>9 QUESTIONS BY MR. HEGARTY:</p> <p>10 Q. Are you aware of anyone in the</p> <p>11 scientific community identifying any</p> <p>12 inaccuracies in the Critical Review paper</p> <p>13 that was published with -- by Drs. Huncharek</p> <p>14 and Muscat?</p> <p>15 A. I think I mentioned it. I</p> <p>16 don't recall any letter to the editor being</p> <p>17 submitted that took exception with anything</p> <p>18 they said in that paper.</p> <p>19 Q. And as to the Critical Review</p> <p>20 paper, have there been other papers published</p> <p>21 that have reached the same conclusions?</p> <p>22 MR. BOWDEN: Objection. Form.</p> <p>23 THE WITNESS: I can't think of</p> <p>24 any now, but I'm totally --</p> <p>25 essentially -- you know, in a way the</p>	<p>1 the data is presented?</p> <p>2 MR. BOWDEN: Objection to form.</p> <p>3 THE WITNESS: Yes.</p> <p>4 QUESTIONS BY MR. HEGARTY:</p> <p>5 Q. And when articles are reviewed</p> <p>6 for peer review, do reviewing scientists</p> <p>7 provide comments on the articles?</p> <p>8 A. In peer review?</p> <p>9 Q. Yes.</p> <p>10 A. It's usually someone from the</p> <p>11 editorial board, and sometimes the editorial</p> <p>12 board will go outside if they don't have</p> <p>13 expertise themselves to review the</p> <p>14 manuscript.</p> <p>15 Q. Is that a proper thing to do</p> <p>16 and standard practice?</p> <p>17 A. Of course, yes.</p> <p>18 MR. BOWDEN: Object to form.</p> <p>19 QUESTIONS BY MR. HEGARTY:</p> <p>20 Q. And does providing comments in</p> <p>21 the course of peer review make the reviewers</p> <p>22 authors, where they need to be included on</p> <p>23 the author line or in the acknowledgement</p> <p>24 section?</p> <p>25 MR. BOWDEN: Objection. Form.</p>

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<p style="text-align: right;">Page 506</p> <p>1 THE WITNESS: Not at all.</p> <p>2 QUESTIONS BY MR. HEGARTY:</p> <p>3 Q. In your experience, when you</p> <p>4 make comments on a white paper or otherwise,</p> <p>5 does that make you an author?</p> <p>6 MR. BOWDEN: Objection. Form.</p> <p>7 THE WITNESS: No, it does not.</p> <p>8 QUESTIONS BY MR. HEGARTY:</p> <p>9 Q. In the end, is it up to the</p> <p>10 authors to consider the comments and decide</p> <p>11 whether to include any suggestions and make</p> <p>12 them their own?</p> <p>13 A. That is up to them, yes.</p> <p>14 MR. BOWDEN: Objection. Form.</p> <p>15 QUESTIONS BY MR. HEGARTY:</p> <p>16 Q. And to your knowledge, did any</p> <p>17 comments that were made to the white papers</p> <p>18 change the substance of the papers?</p> <p>19 A. Not the substance. I think, as</p> <p>20 I mentioned earlier, Dr. Muscat was not very</p> <p>21 familiar with the mineralogical literature,</p> <p>22 and that was pointed out to him and it got</p> <p>23 straightened out.</p> <p>24 Q. Did any of the comments</p> <p>25 provided actually change the results or</p>	<p style="text-align: right;">Page 508</p> <p>1 QUESTIONS BY MR. HEGARTY:</p> <p>2 Q. And you mentioned earlier that</p> <p>3 Dr. Muscat was there and supported by an</p> <p>4 industry group, the Industrial Minerals</p> <p>5 Association?</p> <p>6 A. Yes.</p> <p>7 Q. And was that allowed under</p> <p>8 IARC's rules?</p> <p>9 A. Yes.</p> <p>10 And there were some Luzenac</p> <p>11 people in that group, too.</p> <p>12 Q. Why does IARC want industry</p> <p>13 observers or sponsor scientists there?</p> <p>14 A. They're a stakeholder,</p> <p>15 essentially, and they -- industry supports</p> <p>16 research and has researchers as well and</p> <p>17 scientists that can contribute, and I would</p> <p>18 think they'd welcome that.</p> <p>19 Q. That was going to be my next</p> <p>20 question.</p> <p>21 Do they actually welcome the</p> <p>22 expertise that the observers can bring to the</p> <p>23 process?</p> <p>24 MR. BOWDEN: Objection to form.</p> <p>25 THE WITNESS: I think they do.</p>
<p style="text-align: right;">Page 507</p> <p>1 conclusions of the papers?</p> <p>2 A. No, it did not.</p> <p>3 Q. Would you ever advocate to</p> <p>4 change data, results or conclusions from a</p> <p>5 study to benefit anyone?</p> <p>6 MR. BOWDEN: Objection. Form.</p> <p>7 THE WITNESS: No, I would not.</p> <p>8 QUESTIONS BY MR. HEGARTY:</p> <p>9 Q. And did that happen here?</p> <p>10 MR. BOWDEN: Objection. Form.</p> <p>11 THE WITNESS: No, it did not.</p> <p>12 QUESTIONS BY MR. HEGARTY:</p> <p>13 Q. You were also asked about your</p> <p>14 involvement in the IARC meeting back in 2006.</p> <p>15 Do you recall those questions?</p> <p>16 A. Yes.</p> <p>17 Q. And from your standpoint as to</p> <p>18 Dr. Muscat's work, did he approach being an</p> <p>19 observer as an independent scientist with</p> <p>20 his -- where his contributions were based</p> <p>21 solely on the data and not being an advocate</p> <p>22 of any position?</p> <p>23 MR. BOWDEN: Objection to form.</p> <p>24 THE WITNESS: Yes.</p> <p>25</p>	<p style="text-align: right;">Page 509</p> <p>1 QUESTIONS BY MR. HEGARTY:</p> <p>2 Q. We asked -- strike that.</p> <p>3 You were asked about Dr. Muscat</p> <p>4 making comments as an observer as to the data</p> <p>5 regarding talc pleurodesis.</p> <p>6 Do you recall those questions?</p> <p>7 A. I'm sorry, I was drifting off.</p> <p>8 Q. That's all right. I'll try to</p> <p>9 finish very quickly.</p> <p>10 A. That's all right.</p> <p>11 Q. Do you recall Dr. Muscat --</p> <p>12 strike that.</p> <p>13 Do you recall questions being</p> <p>14 asked about Dr. Muscat making comments as an</p> <p>15 observer as to use of talc and pleurodesis?</p> <p>16 A. Yes.</p> <p>17 Q. I believe you described a</p> <p>18 little bit what talc pleurodesis is, but</p> <p>19 that's actually injection of talc in a slurry</p> <p>20 into the lung cavity?</p> <p>21 A. It's into the pleural space.</p> <p>22 MR. BOWDEN: Objection to form.</p> <p>23 QUESTIONS BY MR. HEGARTY:</p> <p>24 Q. Into the pleural space?</p> <p>25 A. Yeah, the -- the two membranes</p>

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<p style="text-align: right;">Page 510</p> <p>1 which surround the lung, and there's a small 2 amount of fluid. And if you've ever had 3 pleurisy, you know what the pleura can be. 4 Q. And why was it important for 5 the working group to consider the data on 6 talc used in pleurodesis? 7 MR. BOWDEN: Form. 8 THE WITNESS: I think it has 9 strong relevance to discount the 10 relationship between -- proposed 11 relationship between talc exposure, 12 perineal talc exposure, and ovarian 13 cancer. 14 QUESTIONS BY MR. HEGARTY: 15 Q. In fact, if talc was a 16 carcinogen, what would you expect to see from 17 that data? 18 MR. BOWDEN: Objection. Form. 19 Calls for an opinion. 20 THE WITNESS: You would -- you 21 would expect to see anyone that had a 22 longevity of probably ten years, after 23 undergoing pleurodesis, dead. 24 QUESTIONS BY MR. HEGARTY: 25 Q. But what did the data show</p>	<p style="text-align: right;">Page 512</p> <p>1 Dr. Muscat do what observers are expected to 2 do: provide information that might be 3 helpful to the working group as part of 4 evaluating the issue? 5 A. Yes. 6 MR. BOWDEN: Form. 7 QUESTIONS BY MR. HEGARTY: 8 Q. Counsel for plaintiffs kept 9 referring to the talc pleurodesis data as 10 your strategy. But just to make clear, the 11 data that we've been talking about is data 12 that was generated by scientists who were 13 looking at this issue before you ever looked 14 at the issue, correct? 15 A. Yeah, I -- 16 MR. BOWDEN: Objection to form. 17 THE WITNESS: I thought of it 18 because of my experience with my son 19 undergoing an open thoracotomy and 20 talc installation. And so I started 21 researching the literature, and that's 22 where I found the British study, the 23 Lange study, and one other study, and 24 I thought those could be buttressed by 25 a more sound -- by a stronger study.</p>
<p style="text-align: right;">Page 511</p> <p>1 instead? 2 A. It showed that it does not have 3 an effect. 4 Q. What did that say about the 5 association between talc use and ovarian 6 cancer? 7 MR. BOWDEN: Objection to form. 8 Calls for expert testimony. 9 THE WITNESS: I think that -- I 10 think it is -- you can relate that. 11 You can transfer that knowledge to the 12 epithelial ovarian cells as well. 13 QUESTIONS BY MR. HEGARTY: 14 Q. Did the panel working group 15 accept the data on talc use as pleurodesis? 16 A. I think they were enlightened 17 by it. I believe it's possible that 18 Dr. Antony, who was on another panel, was 19 asked by the epidemiology group to come give 20 them a pleurodesis 101. 21 And in fact, IARC brought in a 22 researcher who wasn't on a working group who 23 had done research in that area, too. I think 24 her name was Dr. Dressler. 25 Q. And in providing that data, did</p>	<p style="text-align: right;">Page 513</p> <p>1 QUESTIONS BY MR. HEGARTY: 2 Q. In essence, you found that you 3 weren't the first one to think about that? 4 MR. BOWDEN: Objection to form. 5 THE WITNESS: Yeah, I can't 6 take credit totally for it. 7 QUESTIONS BY MR. HEGARTY: 8 Q. In fact, you found a number of 9 studies where the authors thought that the 10 results of that data was relevant to show 11 that talc doesn't cause cancer? 12 MR. BOWDEN: Form. 13 THE WITNESS: Yes. And then 14 when I -- when I found Dr. Antony and 15 met with her at the American Thoracic 16 Society, I was more reinforced by her 17 that there's not a relationship. 18 QUESTIONS BY MR. HEGARTY: 19 Q. You were not the source, 20 though, of any that data. 21 A. No. 22 Q. That data was in the public 23 domain? 24 A. Yes. 25 Q. And was that data available to</p>



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<p style="text-align: right;">Page 514</p> <p>1 anyone who wanted to review it?</p> <p>2 A. Yes.</p> <p>3 MR. BOWDEN: Objection. Form.</p> <p>4 QUESTIONS BY MR. HEGARTY:</p> <p>5 Q. Now, we talked a moment ago</p> <p>6 about IARC's conclusions from the</p> <p>7 proceedings, and that was that they</p> <p>8 categorized talc as 2B, possibly</p> <p>9 carcinogenic, correct?</p> <p>10 A. Yes.</p> <p>11 Q. IARC did not conclude that talc</p> <p>12 is a carcinogen, correct?</p> <p>13 MR. BOWDEN: Objection to form.</p> <p>14 THE WITNESS: No.</p> <p>15 QUESTIONS BY MR. HEGARTY:</p> <p>16 Q. Did IARC conclude that talc is</p> <p>17 a probable carcinogen?</p> <p>18 A. No.</p> <p>19 Q. In terms of classifying talc as</p> <p>20 category B, has IARC classified a number of</p> <p>21 substances that we as a public consume or use</p> <p>22 every day? In particular, did it classify</p> <p>23 coffee as 2B?</p> <p>24 MR. BOWDEN: Objection. Form.</p> <p>25 THE WITNESS: I believe it did.</p>	<p style="text-align: right;">Page 516</p> <p>1 QUESTIONS BY MR. HEGARTY:</p> <p>2 Q. You were asked a few questions</p> <p>3 about Dr. Muscat's disclosure of his</p> <p>4 interests as part of the IARC process where</p> <p>5 he acted as an observer.</p> <p>6 Do you recall those questions?</p> <p>7 A. I'm sorry.</p> <p>8 Q. That's okay.</p> <p>9 You were asked a couple of</p> <p>10 questions about Dr. Muscat's disclosure of</p> <p>11 his interests as being an observer in the</p> <p>12 IARC proceedings.</p> <p>13 Do you recall that?</p> <p>14 A. Yes.</p> <p>15 Q. Have you had a chance to talk</p> <p>16 to Dr. Muscat about why he made his</p> <p>17 disclosures as an observer as he did?</p> <p>18 A. I have not. I haven't had any</p> <p>19 communication with Joshua in years, probably</p> <p>20 not since I left Crowell &amp; Moring.</p> <p>21 Q. Do you know whether at the time</p> <p>22 of his disclosure if he still considered</p> <p>23 himself to be working under the Crowell &amp;</p> <p>24 Moring contracts?</p> <p>25 MR. BOWDEN: Objection to form.</p>
<p style="text-align: right;">Page 515</p> <p>1 There were a number of dietary things</p> <p>2 that they've looked at and...</p> <p>3 QUESTIONS BY MR. HEGARTY:</p> <p>4 Q. And have they classified</p> <p>5 pickled vegetables as 2B?</p> <p>6 MR. BOWDEN: Form.</p> <p>7 THE WITNESS: I'm taking your</p> <p>8 representation.</p> <p>9 QUESTIONS BY MR. HEGARTY:</p> <p>10 Q. Do you recall they classified</p> <p>11 whole leaf aloe vera as 2B?</p> <p>12 MR. BOWDEN: Objection.</p> <p>13 THE WITNESS: And probably if</p> <p>14 they looked at smoked meat they would</p> <p>15 do that. I don't know if they have.</p> <p>16 QUESTIONS BY MR. HEGARTY:</p> <p>17 Q. I believe they may have</p> <p>18 classified red meat as probably carcinogenic.</p> <p>19 Are you familiar with that?</p> <p>20 A. Yes, I think they did.</p> <p>21 Q. But in the end, did they</p> <p>22 classify talc as a carcinogen or even a</p> <p>23 probable carcinogen?</p> <p>24 MR. BOWDEN: Objection to form.</p> <p>25 THE WITNESS: No, they did not.</p>	<p style="text-align: right;">Page 517</p> <p>1 THE WITNESS: I don't know. As</p> <p>2 I say, he was -- his freight was paid</p> <p>3 by IMA.</p> <p>4 QUESTIONS BY MR. HEGARTY:</p> <p>5 Q. Was -- would Dr. Muscat be the</p> <p>6 best source of information to answer</p> <p>7 questions as to why he made the disclosure</p> <p>8 that he did the way he did?</p> <p>9 MR. BOWDEN: Objection. Form.</p> <p>10 THE WITNESS: Yes, he</p> <p>11 absolutely would.</p> <p>12 QUESTIONS BY MR. HEGARTY:</p> <p>13 Q. So would you defer to him as</p> <p>14 far as the reason he included in his</p> <p>15 disclosure the Industrial Minerals</p> <p>16 Association?</p> <p>17 A. Most certainly.</p> <p>18 MR. HEGARTY: Go off the record</p> <p>19 for a minute.</p> <p>20 VIDEOGRAPHER: Going off the</p> <p>21 record at 6:02. Going off the record.</p> <p>22 (Off the record at 6:02 p.m.)</p> <p>23 VIDEOGRAPHER: Okay. The time</p> <p>24 is now 6:04. Back on record.</p> <p>25</p>

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<p style="text-align: right;">Page 518</p> <p>1 QUESTIONS BY MR. HEGARTY:</p> <p>2 Q. Mr. Glenn, just a few more</p> <p>3 questions, then I'll be finished.</p> <p>4 You were asked a number of</p> <p>5 questions about J&amp;J and its activities and</p> <p>6 shown a number of documents that made</p> <p>7 reference to J&amp;J, in particular Steven Mann.</p> <p>8 Do you recall those questions</p> <p>9 and those documents?</p> <p>10 A. Yes, I do.</p> <p>11 Q. Mr. Glenn, have you ever worked</p> <p>12 for Johnson &amp; Johnson?</p> <p>13 A. No, I have not.</p> <p>14 Q. And again, you were shown a</p> <p>15 number of documents by plaintiff's counsel,</p> <p>16 but have you had a chance to review the</p> <p>17 hundreds and thousands of other documents</p> <p>18 that have been provided by Johnson &amp; Johnson</p> <p>19 to plaintiff's counsel concerning studies,</p> <p>20 funding, the science and other issues we</p> <p>21 discussed today?</p> <p>22 MR. BOWDEN: Objection. Form.</p> <p>23 THE WITNESS: No, I have not.</p> <p>24 QUESTIONS BY MR. HEGARTY:</p> <p>25 Q. And were you ever involved in</p>	<p style="text-align: right;">Page 520</p> <p>1 MR. BOWDEN: Objection.</p> <p>2 THE WITNESS: Yes, they were.</p> <p>3 QUESTIONS BY MR. HEGARTY:</p> <p>4 Q. And was that important because</p> <p>5 of concerns that the science was being</p> <p>6 misunderstood and/or not being properly</p> <p>7 characterized?</p> <p>8 MR. BOWDEN: Objection. Form.</p> <p>9 THE WITNESS: Yes, that's</p> <p>10 correct.</p> <p>11 QUESTIONS BY MR. HEGARTY:</p> <p>12 Q. And from your standpoint, when</p> <p>13 the science was properly understood and</p> <p>14 characterized, did it show unequivocally that</p> <p>15 talcum powder is safe to use?</p> <p>16 MR. BOWDEN: Objection. Form.</p> <p>17 THE WITNESS: In my opinion it</p> <p>18 did, as well as many other scientists</p> <p>19 hold the same opinion.</p> <p>20 QUESTIONS BY MR. HEGARTY:</p> <p>21 Q. Did that science, when properly</p> <p>22 understood and characterized, show that</p> <p>23 talcum powder products do not cause ovarian</p> <p>24 cancer?</p> <p>25 MR. BOWDEN: Objection. Form.</p>
<p style="text-align: right;">Page 519</p> <p>1 any decision-making process at Johnson &amp;</p> <p>2 Johnson concerning the funding of studies?</p> <p>3 A. No, I was not.</p> <p>4 Q. As to the communication that</p> <p>5 you were shown involving Steven Mann, did you</p> <p>6 ever speak to Mr. Mann about those</p> <p>7 communications or any internal discussions or</p> <p>8 decision-making processes at Johnson &amp;</p> <p>9 Johnson as they relate to the funding of</p> <p>10 studies?</p> <p>11 A. No, I did not, and I don't</p> <p>12 think I ever person -- in person met Steven</p> <p>13 Mann.</p> <p>14 Q. In fact, can you speak for</p> <p>15 Mr. Mann as to the words he chose or what he</p> <p>16 meant by any of the documents you looked at</p> <p>17 today?</p> <p>18 MR. BOWDEN: Objection. Form.</p> <p>19 THE WITNESS: No way.</p> <p>20 QUESTIONS BY MR. HEGARTY:</p> <p>21 Q. And from your standpoint, were</p> <p>22 both Johnson &amp; Johnson and Imerys properly</p> <p>23 focused on evaluating the science and getting</p> <p>24 the science out there so that everyone can</p> <p>25 make a well-informed decision?</p>	<p style="text-align: right;">Page 521</p> <p>1 THE WITNESS: Yes. Yes.</p> <p>2 QUESTIONS BY MR. HEGARTY:</p> <p>3 Q. And would any decision by NTP</p> <p>4 or IARC concluding otherwise, in your view,</p> <p>5 have been wrong and actually provided a</p> <p>6 disservice to the public?</p> <p>7 MR. BOWDEN: Objection to form.</p> <p>8 THE WITNESS: Yes, it would.</p> <p>9 MR. HEGARTY: Okay. That's all</p> <p>10 the questions I have. Thank you.</p> <p>11 VIDEOGRAPHER: The time is now</p> <p>12 6:07. Going off the record.</p> <p>13 (Off the record at 6:07 p.m.)</p> <p>14 VIDEOGRAPHER: All right. Time</p> <p>15 is now 6:10. Back on the record.</p> <p>16 CROSS-EXAMINATION</p> <p>17 QUESTIONS BY MR. BILLINGS-KANG:</p> <p>18 Q. Hello, Mr. Glenn. How are you</p> <p>19 today?</p> <p>20 A. Just fine.</p> <p>21 Q. My name is James Billings-Kang.</p> <p>22 I represent Personal Care Products Council.</p> <p>23 Now, you and I have never met</p> <p>24 before today; is that correct?</p> <p>25 A. We have not.</p>



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<p>1 Q. In fact, during the break off 2 the record, you asked me who I represented. 3 Do you recall that I mentioned 4 that I represent Personal Care Products 5 Council? 6 A. I do. 7 Q. And do you recall that you 8 mentioned -- you didn't know who that was? 9 MR. BOWDEN: Objection to form. 10 THE WITNESS: It went by 11 another name, mostly, when I was 12 involved with the Cosmetic Toiletries 13 Fragrance Association. 14 QUESTIONS BY MR. BILLINGS-KANG: 15 Q. And it was I who represented 16 that to you -- 17 A. Yes. 18 Q. -- that it was formerly called 19 the CTFA; is that correct? 20 A. Right. Right. 21 Q. Do you know when the CTFA 22 changed its name? 23 A. I do not. 24 Q. Well, I'll represent to you 25 that it changed its name in 2007.</p>	<p>1 them in person? 2 A. I may have met Dr. Loretz, but 3 I don't really recall that I did. 4 Q. Was it a private meeting? 5 A. It would have been a business 6 meeting on the science issue, but not 7 private, no. It would have been a group. 8 Q. Who else would have been in 9 that meeting? 10 A. Probably others that have 11 appeared in some of these documents today and 12 the e-mails and such. 13 Q. Would it have been other people 14 besides PCPC representatives and employees? 15 A. Yes, it could be. 16 Q. Now, have you ever directly, 17 privately, corresponded with Dr. Loretz or 18 anyone from CTFA or PCPC? 19 A. You say privately? 20 Q. Correct, one -- 21 A. No. 22 Q. For instance -- 23 A. No. One communication, no. 24 Q. Just to clarify -- 25 A. Yeah.</p>
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<p>1 A. Oh. 2 Q. So based on that name change, 3 is it -- is it right to infer that you had no 4 communication with CTFA or PCPC after 2007? 5 MR. BOWDEN: Objection to form. 6 THE WITNESS: It would have 7 been around that time. 8 QUESTIONS BY MR. BILLINGS-KANG: 9 Q. Okay. So the last time -- when 10 was the last time you think, if you can 11 approximate? 12 A. It would have been near that 13 time. You know, the correspondence we saw, I 14 would have to go back through and find a 15 date. 16 But Dr. Loretz, I believe, 17 and -- was involved in some of that, but I 18 haven't had any contact lately. 19 Q. Aside from Dr. Loretz, do you 20 know anyone else who was ever employed or 21 represented PCPC or CTFA? 22 A. I might, but I think there was 23 a Kathleen Willy that was involved in some of 24 the phone calls, possibly. 25 Q. And had you ever met either of</p>	<p>1 Q. -- no one else beyond PCPC or 2 CTFA in these communications have you ever 3 had a direct correspondence? 4 A. No. 5 Q. Now, have you ever been 6 employed by CTFA or PCPC? 7 A. No, I have not. 8 Q. Have you ever entered into any 9 agreement with PCPC? 10 A. No, I have not. 11 Q. Have you ever had any 12 communication concerning PCPC's funding of 13 studies? 14 MR. BOWDEN: Objection. Form. 15 THE WITNESS: I have not had 16 any internal communications with them 17 about their funding of studies, no. 18 QUESTIONS BY MR. BILLINGS-KANG: 19 Q. And have you ever received a 20 payment from PCPC or CTFA? 21 A. I have not in any capacity, no. 22 Q. Mr. Glenn, do you know where 23 PCPC's office is at? 24 A. I do not. I know it's in 25 Washington, DC.</p>

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<p>1 Q. Have you ever been to any 2 former office location at all? 3 A. No, I have not. 4 Q. And have you ever been directed 5 by PCPC in any way? 6 A. No. 7 Q. Now, of course there were lots 8 of discussions about -- I'm going to talk 9 about the two white papers by Huncharek and 10 Muscat. 11 A. Yeah. 12 Q. Are you aware of any 13 involvement by CTFA or PCPC with those two 14 white papers? 15 A. I don't recall any -- receiving 16 any comments from them on those papers at 17 all. 18 Q. Okay. So from your standpoint, 19 PCPC or CTFA did not provide any comments or 20 edits to any of those two white papers? 21 A. No, I don't believe they did. 22 MR. BILLINGS-KANG: I think 23 that's all I have, and good luck 24 against the Wolfpack. 25 THE WITNESS: Oh, thank you.</p>	<p>1 questions asking about consumers, right? 2 Customers? 3 A. Yes. 4 Q. All right. And I believe your 5 testimony was along the lines of that one of 6 objectives of Luzenac at the time was to work 7 closely with body powder customers to ensure 8 a coordinated approach, right? 9 A. That was in their strategy, 10 yes. 11 Q. Right. 12 And so the coordinated approach 13 was the industry's position on whether talc 14 causes ovarian cancer, correct? 15 MR. HEGARTY: Objection to 16 form. 17 MR. DONATH: Objection. Form. 18 THE WITNESS: No, I don't think 19 that was what they meant in this 20 document. 21 QUESTIONS BY MR. BOWDEN: 22 Q. What do you think they meant in 23 this document? 24 A. I don't have any idea what they 25 meant, but I don't think that was it based</p>
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<p>1 MR. BOWDEN: Take a brief break 2 if that's all right. 3 VIDEOGRAPHER: The time is now 4 6:15. Going off the record. 5 (Off the record at 6:15 p.m.) 6 VIDEOGRAPHER: Okay. The time 7 is now 6:22. Back on the record. 8 REDIRECT EXAMINATION 9 QUESTIONS BY MR. BOWDEN: 10 Q. All right, Mr. Glenn, we're in 11 the homestretch here. 12 A. Okay. 13 Q. I'm going to ask you to turn to 14 Exhibit 29. 15 A. All right. 16 Q. That's P1.0188. 17 A. Yeah, I have it. 18 Q. And you recall that counsel 19 just a moment ago showed you this document? 20 Remember just discussing this with him? 21 A. Yes. 22 Q. I want you to go to page 3 23 and -- where it says "Objectives"? 24 A. Yes. 25 Q. Counsel and you had a series of</p>	<p>1 upon the content of the other documents, some 2 which are very laudable. 3 Q. Have you ever heard the company 4 say anything other than their position being 5 that ovarian cancer is not caused by talc? 6 MR. DONATH: Objection. Form. 7 MR. HEGARTY: Objection. Form. 8 THE WITNESS: The Rio Tinto or 9 Luzenac saying that? 10 QUESTIONS BY MR. BOWDEN: 11 Q. Yes, sir. 12 A. I'm sorry, state the question. 13 I'm just -- it's been a long day. 14 Q. I know. And I promise you I'm 15 going to keep this brief for you. 16 A. All right. Okay. 17 Q. My question though is -- strike 18 that. 19 When you were having a 20 discussion with counsel about these 21 objectives -- 22 A. Yes. 23 Q. -- you pointed out that we went 24 through a couple of bullet points but not all 25 of them, right?</p>

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<p style="text-align: right;">Page 530</p> <p>1 A. Yes.</p> <p>2 Q. You made that point?</p> <p>3 A. Yes.</p> <p>4 Q. And then he went through and</p> <p>5 said, "The other objectives are to provide</p> <p>6 information to customers and their employees</p> <p>7 and consumers to ensure the safe handling and</p> <p>8 use of talc."</p> <p>9 A. Yes.</p> <p>10 Q. All right. What, if anything,</p> <p>11 after the IARC proceedings did you see Imerys</p> <p>12 do differently as it relates to information</p> <p>13 being given to employees and consumers?</p> <p>14 MR. DONATH: Objection to form.</p> <p>15 THE WITNESS: Yeah, I was not</p> <p>16 involved with them much after that. I</p> <p>17 don't know what they did. I don't</p> <p>18 know if they carried out this strategy</p> <p>19 or not.</p> <p>20 QUESTIONS BY MR. BOWDEN:</p> <p>21 Q. The answer is that as you sit</p> <p>22 here today nothing, right?</p> <p>23 MR. DONATH: Objection to form.</p> <p>24 MR. DAVANT: Objection.</p> <p>25 MR. BILLINGS-KANG: Objection.</p>	<p style="text-align: right;">Page 532</p> <p>1 QUESTIONS BY MR. BOWDEN:</p> <p>2 Q. Okay. I just want to be clear.</p> <p>3 A. That's not to say they didn't</p> <p>4 implement parts of it. I just don't know.</p> <p>5 Q. "Develop credible messages and</p> <p>6 identify third-party spokespeople to present</p> <p>7 Rio Tinto Minerals' and other agencies' view</p> <p>8 that there is insufficient evidence that talc</p> <p>9 is unsafe."</p> <p>10 Do you know if they implemented</p> <p>11 that strategy?</p> <p>12 A. I do not know.</p> <p>13 Q. What are the consequences if</p> <p>14 their view is wrong?</p> <p>15 MR. DONATH: Objection to form.</p> <p>16 QUESTIONS BY MR. BOWDEN:</p> <p>17 Q. What are the consequences if</p> <p>18 their view is wrong?</p> <p>19 MR. DONATH: Same objection.</p> <p>20 QUESTIONS BY MR. BOWDEN:</p> <p>21 Q. Their view being the talc does</p> <p>22 not increase the risk of ovarian cancer?</p> <p>23 MR. HEGARTY: Objection. Form.</p> <p>24 THE WITNESS: I don't think it</p> <p>25 does.</p>
<p style="text-align: right;">Page 531</p> <p>1 THE WITNESS: I don't know.</p> <p>2 QUESTIONS BY MR. BOWDEN:</p> <p>3 Q. You can't give me one single</p> <p>4 item, one list -- if we were to make a list</p> <p>5 of what did they do following the IARC</p> <p>6 proceedings to inform consumers that the IARC</p> <p>7 had considered talc to be a 2B carcinogen,</p> <p>8 you can't name a single thing, can you?</p> <p>9 MR. BILLINGS-KANG: Objection.</p> <p>10 Form.</p> <p>11 MR. DONATH: Objection. Form.</p> <p>12 Asked and answered.</p> <p>13 THE WITNESS: I can't answer</p> <p>14 that. I don't know what they did. I</p> <p>15 just know that this was their</p> <p>16 strategy.</p> <p>17 QUESTIONS BY MR. BOWDEN:</p> <p>18 Q. Right.</p> <p>19 But you don't know if they ever</p> <p>20 implemented the strategy?</p> <p>21 A. Of course not.</p> <p>22 Q. Okay.</p> <p>23 MR. DONATH: Objection to form.</p> <p>24 THE WITNESS: I don't.</p> <p>25</p>	<p style="text-align: right;">Page 533</p> <p>1 QUESTIONS BY MR. BOWDEN:</p> <p>2 Q. I'm not asking you if it does.</p> <p>3 I'm asking you if they're wrong, what are the</p> <p>4 consequences?</p> <p>5 A. I'm not going to speculate on</p> <p>6 what the consequence would be.</p> <p>7 Q. Well, one of the consequences</p> <p>8 might be that women continue to use their</p> <p>9 product and get ovarian cancer, right?</p> <p>10 MR. DONATH: Objection to form.</p> <p>11 THE WITNESS: That's your</p> <p>12 opinion, yes.</p> <p>13 QUESTIONS BY MR. BOWDEN:</p> <p>14 Q. If talc increases the risk of</p> <p>15 ovarian cancer and the industry's view on</p> <p>16 this is wrong, that it doesn't, the</p> <p>17 consequence of being wrong is that women</p> <p>18 continue to apply a carcinogen to their</p> <p>19 bodies, correct?</p> <p>20 MR. HEGARTY: Objection. Asked</p> <p>21 and answered.</p> <p>22 MR. DONATH: Objection to form.</p> <p>23 MR. BILLINGS-KANG: Objection</p> <p>24 to form.</p> <p>25 THE WITNESS: They might choose</p>

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<p>1 to do that, yes.</p> <p>2 QUESTIONS BY MR. BOWDEN:</p> <p>3 Q. And let's just be, I mean, very</p> <p>4 candid here. Baby powder, body powder, you</p> <p>5 don't have to use talc to make it.</p> <p>6 MR. HEGARTY: Objection. Form.</p> <p>7 MR. DONATH: Objection to form.</p> <p>8 QUESTIONS BY MR. BOWDEN:</p> <p>9 Q. You understand that cornstarch</p> <p>10 is offered by some other companies, right?</p> <p>11 A. I don't know about cornstarch.</p> <p>12 I know about talc.</p> <p>13 Q. But you don't know about --</p> <p>14 A. You brought up a good point.</p> <p>15 You call that baby powder.</p> <p>16 Q. I'm talking about talcum</p> <p>17 powder.</p> <p>18 A. I'm sorry.</p> <p>19 Q. No, sir, this is not your</p> <p>20 opportunity --</p> <p>21 A. You said baby -- you said baby</p> <p>22 powder.</p> <p>23 Q. Yeah, products like Johnson &amp;</p> <p>24 Johnson baby powder.</p> <p>25 A. It brought up a question that I</p>	<p>1 Q. Okay.</p> <p>2 A. From perineal application of</p> <p>3 powder, body powder.</p> <p>4 Q. And do you feel that the</p> <p>5 industry has voiced that view as strongly as</p> <p>6 you have just now?</p> <p>7 MR. HEGARTY: Objection. Form.</p> <p>8 MR. DONATH: Objection.</p> <p>9 THE WITNESS: The industry</p> <p>10 might not be as emotional as I am.</p> <p>11 You've tried to...</p> <p>12 QUESTIONS BY MR. BOWDEN:</p> <p>13 Q. All right. So --</p> <p>14 A. You've tried to impugn my</p> <p>15 integrity throughout this thing, and I'm</p> <p>16 tired of it.</p> <p>17 MR. BOWDEN: Move to strike the</p> <p>18 comments.</p> <p>19 QUESTIONS BY MR. BOWDEN:</p> <p>20 Q. Now, you had asked -- you had</p> <p>21 had some questions asked by counsel about</p> <p>22 there being studies that showed an increased</p> <p>23 risk of ovarian cancer and studies that</p> <p>24 didn't show an increased risk of ovarian</p> <p>25 cancer, right?</p>
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<p>1 have --</p> <p>2 Q. Sir, you don't get to ask</p> <p>3 questions.</p> <p>4 A. -- and that is -- no, all</p> <p>5 right, I won't ask a question. I'll</p> <p>6 formulate something.</p> <p>7 Q. Sir, you don't get to --</p> <p>8 A. All -- where are all the --</p> <p>9 where are all the mesotheliomas from babies</p> <p>10 that were powdered -- had their butts</p> <p>11 powdered for two or three years with baby</p> <p>12 powder, talcum powder? Where are they?</p> <p>13 Q. Are you done?</p> <p>14 A. Yes.</p> <p>15 MR. BOWDEN: I move to strike</p> <p>16 your nonresponsive answer.</p> <p>17 QUESTIONS BY MR. BOWDEN:</p> <p>18 Q. All right. The consequence is</p> <p>19 that if they're wrong, you would be</p> <p>20 subjecting people --</p> <p>21 A. I don't think it's a risk.</p> <p>22 Q. We understand that that's your</p> <p>23 opinion.</p> <p>24 A. Sir, I don't think they are</p> <p>25 subjected to any risk.</p>	<p>1 A. Yes.</p> <p>2 MR. HEGARTY: Objection. Form.</p> <p>3 QUESTIONS BY MR. BOWDEN:</p> <p>4 Q. And you would agree with me</p> <p>5 that there are studies on both sides of the</p> <p>6 issue?</p> <p>7 A. And I think there are more on</p> <p>8 the negative side. So weight of the evidence</p> <p>9 is it does not.</p> <p>10 Q. I understand that's your</p> <p>11 opinion today. I'm not asking your opinion.</p> <p>12 A. That's the opinion of other</p> <p>13 scientists as well. Many.</p> <p>14 Q. Okay. And there are -- there</p> <p>15 are scientists that have opinions that differ</p> <p>16 from yours, correct?</p> <p>17 MR. HEGARTY: Objection.</p> <p>18 MR. DONATH: Objection. Form.</p> <p>19 THE WITNESS: Yes, and many of</p> <p>20 them are getting paid lots of money by</p> <p>21 plaintiffs' firms.</p> <p>22 QUESTIONS BY MR. BOWDEN:</p> <p>23 Q. IARC's being paid by</p> <p>24 plaintiffs' firms?</p> <p>25 A. No, not IARC.</p>

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<p style="text-align: right;">Page 538</p> <p>1 Q. Okay.</p> <p>2 A. I said expert.</p> <p>3 Q. So --</p> <p>4 A. Hankinson may be. I don't know</p> <p>5 for sure.</p> <p>6 Q. You don't know; you're just</p> <p>7 guessing?</p> <p>8 A. Yeah, I'm just guessing.</p> <p>9 Q. Okay. And why would you</p> <p>10 believe that to be a guess?</p> <p>11 A. Well, she was on the IARC</p> <p>12 working group.</p> <p>13 Q. Okay.</p> <p>14 A. And she was strong in her</p> <p>15 conviction that studies of her group and</p> <p>16 Dr. Cramer were solid, and I don't think they</p> <p>17 are. I think there are methodological</p> <p>18 problems with it.</p> <p>19 Q. And so because she -- her</p> <p>20 opinion differs from yours, you suspect that</p> <p>21 she might be being paid by someone else?</p> <p>22 MR. DONATH: Objection. Form.</p> <p>23 THE WITNESS: The way it is</p> <p>24 now, I'm not sure why she's been on</p> <p>25 the working group.</p>	<p style="text-align: right;">Page 540</p> <p>1 QUESTIONS BY MR. BOWDEN:</p> <p>2 Q. So why is funding important to</p> <p>3 you? You just brought this up on your own.</p> <p>4 Why is it important to you?</p> <p>5 A. It can be important.</p> <p>6 Q. It can be a source of bias,</p> <p>7 right?</p> <p>8 MR. DONATH: Objection. Form.</p> <p>9 THE WITNESS: It may be in some</p> <p>10 cases.</p> <p>11 QUESTIONS BY MR. BOWDEN:</p> <p>12 Q. Okay. And you were actually</p> <p>13 paid, weren't you?</p> <p>14 A. Pardon?</p> <p>15 Q. From 2004 to 2010, during those</p> <p>16 IARC proceedings, you were actually being</p> <p>17 paid?</p> <p>18 A. Yes, I was.</p> <p>19 Q. And your paycheck was coming</p> <p>20 from Crowell &amp; Moring, correct?</p> <p>21 A. Yes.</p> <p>22 Q. From funds given to Crowell &amp;</p> <p>23 Moring for your services by Luzenac, true?</p> <p>24 MR. DONATH: Objection to form.</p> <p>25 THE WITNESS: Yes.</p>
<p style="text-align: right;">Page 539</p> <p>1 QUESTIONS BY MR. BOWDEN:</p> <p>2 Q. Well, that's an interesting</p> <p>3 point that you bring up. Payment from</p> <p>4 somebody else, undisclosed payment, that's a</p> <p>5 consideration that you take into account when</p> <p>6 weighing their opinions?</p> <p>7 MR. HEGARTY: Objection. Form.</p> <p>8 QUESTIONS BY MR. BOWDEN:</p> <p>9 Q. Is that what you're telling our</p> <p>10 jury?</p> <p>11 A. I've said it enough.</p> <p>12 Q. No, no, no. You're going to</p> <p>13 answer that question.</p> <p>14 A. No.</p> <p>15 Q. When someone has payments to</p> <p>16 them, you want to know who those payments are</p> <p>17 from when they're forming their opinions so</p> <p>18 you can weigh the veracity of the opinions</p> <p>19 and their conclusions?</p> <p>20 MR. HEGARTY: Objection. Form.</p> <p>21 Asked and answered.</p> <p>22 MR. DONATH: Objection.</p> <p>23 THE WITNESS: I want to know</p> <p>24 the veracity of their opinions, is</p> <p>25 most important.</p>	<p style="text-align: right;">Page 541</p> <p>1 QUESTIONS BY MR. BOWDEN:</p> <p>2 Q. And during that time period you</p> <p>3 voiced an opinion about talc and ovarian</p> <p>4 cancer risk, correct?</p> <p>5 A. Yes.</p> <p>6 Q. All right. So it's not unusual</p> <p>7 for a scientist to interpret data</p> <p>8 differently, correct?</p> <p>9 MR. HEGARTY: Objection. Form.</p> <p>10 MR. DONATH: Objection.</p> <p>11 THE WITNESS: That's correct.</p> <p>12 QUESTIONS BY MR. BOWDEN:</p> <p>13 Q. That's part of the scientific</p> <p>14 debate?</p> <p>15 A. Debate, that's correct.</p> <p>16 Q. And in fact, for years --</p> <p>17 actually, you mentioned Dr. Wynder earlier,</p> <p>18 right?</p> <p>19 A. Dr. Ernst Wynder.</p> <p>20 Q. Wynder?</p> <p>21 A. Yes.</p> <p>22 Q. And you would agree with me</p> <p>23 that there were consultants, for example, for</p> <p>24 the tobacco industry that for years stated</p> <p>25 there was no connection between cigarette</p>



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<p style="text-align: right;">Page 542</p> <p>1 smoke and lung cancer. 2 You would agree with me on 3 that? 4 MR. HEGARTY: Objection. Form. 5 THE WITNESS: There were some, 6 yes. 7 QUESTIONS BY MR. BOWDEN: 8 Q. Right. 9 And in fact, there weren't just 10 some; there was a lot? 11 MR. DONATH: Objection. Form. 12 THE WITNESS: There were a 13 number, yes. 14 QUESTIONS BY MR. BOWDEN: 15 Q. Right. 16 And it was something that was 17 used to create doubt -- 18 MR. DONATH: Objection. Form. 19 MR. HEGARTY: Objection. Form. 20 QUESTIONS BY MR. BOWDEN: 21 Q. -- over decades and decades and 22 decades, right? 23 A. It was misleading, yes. 24 Q. Right. 25 And when they turned out to be</p>	<p style="text-align: right;">Page 544</p> <p>1 industry's view that tobacco smoking did not 2 increase the risk of lung cancer. 3 You're aware of that as a fact 4 as you sit here? 5 MR. DONATH: Objection. Form. 6 MR. HEGARTY: Objection. Form. 7 THE WITNESS: Yes, and it was 8 criminal. 9 QUESTIONS BY MR. BOWDEN: 10 Q. It was criminal. 11 The consequences for their view 12 being wrong was the death of hundreds of 13 thousands of individuals, correct? 14 MR. DONATH: Objection. Form. 15 MR. HEGARTY: Objection. Form. 16 QUESTIONS BY MR. BOWDEN: 17 Q. It led to the death and disease 18 of human beings? 19 A. Yes, it did. Yes. 20 MR. DONATH: Objection to form. 21 QUESTIONS BY MR. BOWDEN: 22 Q. Okay. And so in that specific 23 example, there were people on both sides of 24 that issue as well, true? 25 MR. HEGARTY: Objection. Form.</p>
<p style="text-align: right;">Page 543</p> <p>1 wrong -- you're not going to sit here today 2 and tell us that smoking doesn't increase the 3 risk of lung cancer, right? 4 MR. HEGARTY: Objection. Form. 5 THE WITNESS: No, but I would 6 say that breast implants don't produce 7 any -- any breast disease or breast 8 cancer. That was -- 9 QUESTIONS BY MR. BOWDEN: 10 Q. I don't remember -- 11 A. That went through a number of 12 litigation. Of course in the end it was 13 proved it was not true, not a scientific 14 fact. 15 Q. That's your response to my 16 question of whether -- 17 A. I'm just saying that -- 18 Q. -- cigarette smoke -- 19 A. -- both sides -- 20 Q. Please, sir, don't interrupt 21 me. 22 My question to you is that as 23 you sit here today, you are aware that there 24 were consultants paid for by the tobacco 25 industry which for years espoused the</p>	<p style="text-align: right;">Page 545</p> <p>1 THE WITNESS: There were. 2 QUESTIONS BY MR. BOWDEN: 3 Q. Scientists -- 4 A. Yes. 5 Q. -- who looked at the same data? 6 A. Yes. 7 Q. You would agree with me that a 8 product that may cause cancer, particularly 9 cosmetic products, that consumers should be 10 informed of that possibility? 11 MR. DONATH: Objection. Form. 12 MR. HEGARTY: Objection. Form. 13 THE WITNESS: I don't know what 14 the FDA rules are regarding labeling 15 and warnings to consumers. 16 QUESTIONS BY MR. BOWDEN: 17 Q. I'm not asking you about what 18 the regulations are or what the FDA requires. 19 I'm asking you as you sit here 20 today, you would agree with me that if a 21 product contains something that can cause 22 cancer, particularly if it's in a cosmetic 23 product, that consumers should be informed of 24 that possibility? 25 MR. DONATH: Objection. Form.</p>

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<p>1 Beyond the scope. 2 MR. HEGARTY: Objection. Form. 3 THE WITNESS: If it presents an 4 unacceptable risk, they should be 5 informed. 6 MR. DAVANT: Counsel, you -- 7 QUESTIONS BY MR. BOWDEN: 8 Q. If there's no benefit of the 9 product, is there any amount of risk that's 10 acceptable? 11 MR. HEGARTY: Objection. Asked 12 and answered. 13 THE WITNESS: I'm sorry, what? 14 QUESTIONS BY MR. BOWDEN: 15 Q. If the product itself provides 16 no benefit, is there any amount of risk 17 that's acceptable? 18 MR. BILLINGS-KANG: Asked and 19 answered. 20 MR. DONATH: Objection. Form. 21 Beyond the scope. Asked and answered. 22 THE WITNESS: There's no such 23 thing as, you know, safety. I mean, 24 we all accept risk. 25</p>	<p>1 minutes do you think? Because it's 2 already -- 3 MR. BOWDEN: Well, I don't need 4 to give you a time frame. We have 5 seven hours, and we'll take minute for 6 minute from you've guys have done. 7 Am I bumping up against what 8 you've done? 9 MR. DAVANT: The witness didn't 10 take a minute. And under your 11 protocol, you were supposed to be 12 limited to 15-minute breaks, and you 13 took a lot of breaks today. You took 14 a lot of long breaks. 15 MR. BOWDEN: Are you serious? 16 You want to put on the record the 17 reason for that? 18 MR. DAVANT: Sure. It's you. 19 MR. TISI: All right. Let's 20 just get done. 21 MR. BOWDEN: Whatever. All 22 right. 23 MR. DAVANT: And now you're 24 asking the same questions you've 25 already spent seven hours asking. You</p>
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<p>1 QUESTIONS BY MR. BOWDEN: 2 Q. Risk that they have to know 3 about, right? 4 MR. DAVANT: Counsel. 5 MR. HEGARTY: Objection. Form. 6 QUESTIONS BY MR. BOWDEN: 7 Q. Risks that they should know 8 about, right? 9 MR. DONATH: Objection to form. 10 MR. HEGARTY: Objection. Form. 11 THE WITNESS: If it's an 12 unacceptable risk, they should be 13 informed. 14 QUESTIONS BY MR. BOWDEN: 15 Q. Okay. Unacceptable by whose 16 view? 17 MR. DONATH: Objection. 18 THE WITNESS: Unacceptable 19 by -- it becomes a policy decision. 20 QUESTIONS BY MR. BOWDEN: 21 Q. I see. 22 MR. DAVANT: Counsel, how much 23 more do you have? 24 MR. BOWDEN: Just a little bit. 25 MR. DAVANT: Like how many more</p>	<p>1 spent two hours asking about things 2 that he wasn't involved in. Please 3 try to focus. 4 MR. BOWDEN: Oh, thanks. I 5 appreciate you chiming in now at the 6 end of the deposition. I appreciate 7 it. 8 QUESTIONS BY MR. BOWDEN: 9 Q. Where scientists disagree on 10 the issues such as carcinogens, things that 11 can cause cancer, should companies err on the 12 side of patient safety or business interest? 13 MR. HEGARTY: Objection. Form. 14 MR. DONATH: Objection. Form. 15 THE WITNESS: It's been a long 16 day. Give me that one again. 17 QUESTIONS BY MR. BOWDEN: 18 Q. Where scientists disagree on 19 issues such as the cause of cancer in a 20 product, should companies err on the side of 21 patient safety or business interests? 22 MR. HEGARTY: Objection. Form. 23 MR. DONATH: Objection. Form. 24 Beyond the scope. 25 THE WITNESS: Patients should</p>

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<p style="text-align: right;">Page 550</p> <p>1 side on whether there's an 2 unacceptable risk by their product and 3 its use. 4 MR. BOWDEN: Thank you. Those 5 are my questions. 6 Want some follow-up? 7 VIDEOGRAPHER: The time is now 8 6:35. This concludes the deposition. 9 Going off the record. 10 (Deposition concluded at 6:35 p.m.) 11 ----- 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>	<p style="text-align: right;">Page 552</p> <p>1 INSTRUCTIONS TO WITNESS 2 3 Please read your deposition over 4 carefully and make any necessary corrections. 5 You should state the reason in the 6 appropriate space on the errata sheet for any 7 corrections that are made. 8 After doing so, please sign the 9 errata sheet and date it. You are signing 10 same subject to the changes you have noted on 11 the errata sheet, which will be attached to 12 your deposition. 13 It is imperative that you return 14 the original errata sheet to the deposing 15 attorney within thirty (30) days of receipt 16 of the deposition transcript by you. If you 17 fail to do so, the deposition transcript may 18 be deemed to be accurate and may be used in 19 court. 20 21 22 23 24 25</p>
<p style="text-align: right;">Page 551</p> <p>1 CERTIFICATE 2 3 I, CARRIE A. CAMPBELL, Registered 4 Diplomat Reporter, Certified Realtime 5 Reporter and Certified Shorthand Reporter, do 6 hereby certify that prior to the commencement 7 of the examination, Robert Glenn was duly 8 sworn by me to testify to the truth, the 9 whole truth and nothing but the truth. 10 I DO FURTHER CERTIFY that the 11 foregoing is a verbatim transcript of the 12 testimony as taken stenographically by and 13 before me at the time, place and on the date 14 hereinbefore set forth, to the best of my 15 ability. 16 17 I DO FURTHER CERTIFY that I am 18 neither a relative nor employee nor attorney 19 nor counsel of any of the parties to this 20 action, and that I am neither a relative nor 21 employee of such attorney or counsel, and 22 that I am not financially interested in the 23 action. 24 25  CARRIE A. CAMPBELL, NCRA Registered Diplomat Reporter Certified Realtime Reporter California Certified Shorthand Notary Public Dated: October 22, 2018</p>	<p style="text-align: right;">Page 553</p> <p>1 ACKNOWLEDGMENT OF DEPONENT 2 3 4 I, _____, do 5 hereby certify that I have read the foregoing 6 pages and that the same is a correct 7 transcription of the answers given by me to 8 the questions therein propounded, except for 9 the corrections or changes in form or 10 substance, if any, noted in the attached 11 Errata Sheet. 12 13 _____ 14 Robert Glenn DATE 15 16 Subscribed and sworn to before me this 17 _____ day of _____, 20 _____. 18 My commission expires: _____ 19 Notary Public 20 21 22 23 24 25</p>

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# Exhibit 159



# Use of cosmetic talc on contraceptive diaphragms and risk of ovarian cancer: a meta-analysis of nine observational studies

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Prior work suggests an association between perineal use of cosmetic talc and increased ovarian cancer risk. A meta-analysis was performed to examine this hypothesis by evaluating ovarian cancer risk associated with direct exposure of the female genital tract to talc via dusting of contraceptive diaphragms. Data were pooled from epidemiological studies using a general variance-based meta-analytic method that employs confidence intervals. The outcome of interest was a summary relative risk reflecting the risk of ovarian cancer development associated with the use of cosmetic talc on contraceptive diaphragms. Sensitivity analyses were performed to explain any observed statistical heterogeneity and to explore the influence of specific study characteristics on the summary estimate of effect. Initially, combining homogeneous data from nine case-control studies yielded a non-statistically significant summary relative risk of 1.03 (0.80–1.37), suggesting no association between talc-dusted diaphragms and ovarian cancer development. Sensitivity analyses were performed to evaluate the robustness of this finding. All resultant summary relative

risks were not statistically significant. The available epidemiological data do not support a causal association between the use of cosmetic talc-dusted diaphragms and ovarian cancer development. *European Journal of Cancer Prevention* 16:422–429 © 2007 Lippincott Williams & Wilkins.

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## Introduction

Ovarian cancer represents a major cause of cancer-related morbidity and mortality in the United States with an estimated 22 000 new cases diagnosed in 2005 (Boger-Meigiddo and Weiss, 2005). It is the seventh most common cancer in women and ranks fourth as a cause of cancer deaths among female individuals from the United States, with some 16 000 succumbing to the disease this year. The lethality of ovarian tumors is in large part due to the fact that clinical symptoms tend to occur late in the natural history of the disease and the lack of screening tests allowing for early diagnosis. In fact, approximately 60% of patients are diagnosed with late-stage disease (stage III and IV) vastly diminishing the chance of long-term survival (approximately 10% at 5 years from diagnosis) (Richardson *et al.*, 1985).

Primary prevention of ovarian cancer remains elusive as a clear etiology for the vast majority of cases is unknown. Nonetheless, prior epidemiological research suggests a number of risk factors, including age (older versus younger), nulliparity, first pregnancy after the age of 35 years, diet high in saturated fats, positive family history of

ovarian/breast cancer and race (white versus African American) (Baker and Piver, 1994; Tortolero-Luna and Mitchell, 1995; Daly and Orams, 1998). Clear geographic differences in incidence exist. The highest rates are found in industrialized countries versus underdeveloped nations (Ioka *et al.*, 2003), implicating environmental factors in ovarian cancer etiology. The one exception is highly industrialized Japan (Ioka *et al.*, 2003) with a low annual incidence of approximately 3/100 000. Interestingly, Japanese woman who migrate to the United States experience an increased occurrence of this disease, further suggesting environmental factors in its cause.

In 1982, Cramer *et al.* (1982) published the first study suggesting a link between use of cosmetic talc and the risk of developing ovarian cancer. Subsequently, a number of additional reports have shown a small but increased risk among women using cosmetic talc products, although this finding is not universal (Chang and Risch, 1997). These statistical associations raise concerns that a cause-effect relationship may exist between talc exposure (particularly perineal use) and ovarian carcinogenesis.



Further fueling concerns about this association is the mistaken, but often repeated, assertion that asbestos and talc are biologically similar; that is, they may exhibit similar disease-causing potential (Wong *et al.*, 1999). While talc and asbestos are both silicates, they bear little resemblance structurally or in their biological properties. Asbestos fibers are well recognized human and animal carcinogens with substantial supporting epidemiological and in-vivo evidence available in the published literature (Huncharek, 1986; Mossman and Gee, 1989). Asbestos is known to induce peritoneal (and pleural) mesotheliomas among occupationally and environmentally exposed cohorts and some evidence exists suggesting that asbestos can also cause ovarian neoplasms in humans (Acheson *et al.*, 1982).

Although in the experimental setting translocation of talc particles to the human ovary can occur with deliberate or inadvertent manipulations of patients in the supine position (Wehner, 1998), it is unknown whether cosmetic use of talc in the perineal area can routinely penetrate the female reproductive tract and reach the ovary against physiological forces working in the opposite direction. The existing epidemiological literature focuses primarily on external perineal exposure. It appears, however, that the talc-ovarian cancer hypothesis could be tested with better precision and validity if the exposure to the suspected carcinogen was directly to the reproductive tract. A common route for such an exposure is via talc dusting of contraceptive diaphragms, a well documented practice in the relevant epidemiological literature. Intuitively, the possible association of ovarian cancer with talc-dusted diaphragms appears to provide a more rational test of this cause-effect hypothesis. Therefore, the present report describes the results of a meta-analysis pooling data from nine epidemiological studies examining the risk of ovarian cancer associated with the use of cosmetic talc on diaphragms.

## Methods

The methods employed in the design and execution of this analysis have been previously described (Greenland, 1986; Cooper and Hedges, 1994). A study protocol was prospectively developed outlining the purpose and methods; that is, a meta-analysis examining the risk of developing ovarian cancer associated with use of talc-dusted contraceptive diaphragms. Eligibility criteria for study inclusion were determined prospectively as were the specific data elements to be extracted from each published report. The study protocol included details of the planned statistical analysis.

We used a data extraction form designed for recording relevant information from each selected report. Two researchers performed data extraction with differences in extraction forms resolved by consensus. Other data

collected but not included in the eligibility criteria were the number of patients in each study, study odds ratios or relative risks, 95% confidence intervals and type of statistical adjustments made, if any, by individual study authors.

## Literature search

Information retrieval was performed by previously described methods (Cooper and Hedges, 1994). We conducted a MEDLARS search of the literature published between January 1966 and March 2005, as well as a review of Cancer Lit and the CD-ROM version of Current Contents. The search criteria included all languages. The search terms used were talc exposure and ovarian neoplasms. If a series of articles was published, all data were retrieved from the most recent article. The literature search also included hand searches of bibliographies of published reports, review articles and textbooks.

The initial citations (in the form of abstracts) from this literature search were screened by a physician investigator to exclude those that did not meet inclusion criteria. Reasons for rejection included study designs other than case-control, cohort or randomized controlled trials; animal or in-vivo studies; abstracts; review articles and non-peer reviewed articles. Eligibility criteria included, observational studies or clinical trials enrolling patients with histologically proven ovarian tumors of all histologies, studies enrolling only adult patients (i.e. 18 years or older), availability of data documenting type of talc exposure, in this instance, dusting of diaphragms, and availability of odds ratios or relative risks with 95% confidence intervals for each report or availability of raw data to calculate these parameters.

## Statistical analysis

We performed data analysis according to meta-analytic procedures described by Greenland (1986). This method of meta-analysis is a general variance-based method employing confidence intervals. As the variance estimates are based on the adjusted measures of effect, the confidence interval methods do not ignore confounding and are the preferred methodology for pooling observational studies.

For each included study, we derived odds ratios reflecting the risk of developing ovarian cancer associated with the practice of dusting contraceptive diaphragms with cosmetic talc and determined the natural logarithm of the estimated relative risk for each data set followed by calculation of an estimate of the variance. We used the estimate of the 95% confidence interval from each study to calculate the variance of each study's measure of effect.



We calculated a weight for each included analysis as  $1/\text{variance}$  followed by a summation of the weights. We then determined the product of the study weight and the natural logarithm of the estimated relative risk and performed a summation of these products. Finally, a summary relative risk and 95% confidence interval were determined.

Before the estimation of a summary relative risk, a statistical test for homogeneity was performed ( $Q$ ). This procedure tests the hypothesis that the effect sizes are equal in all of the included studies (Greenland, 1986). If  $Q$  exceeds the upper tail critical value of  $\chi^2$  ( $P < 0.10$ ) at  $k-1$  d.f. (where  $k$  equals the number of studies analyzed or the number of comparisons made), the observed variance in study effect sizes is significantly greater than what would be expected by chance if all studies shared a common population effect size. If the hypothesis that the studies are homogenous is rejected, the studies do not measure an effect of the same size. In this instance, calculation of a pooled estimate of effect (i.e. relative risks) may be of questionable validity. Possible explanations for the observed heterogeneity must be sought to provide the most rational interpretation of the summary relative risk. Sensitivity analyses and or further stratified analyses are then performed based on the magnitude of  $Q$ .

## Results

The literature search yielded 17 studies that appeared to meet protocol specifications and full papers were obtained for review (Hartge *et al.*, 1983; Richardson

*et al.*, 1985; Whittemore *et al.*, 1988; Booth *et al.*, 1989; Harlow and Weiss, 1989; Chen *et al.*, 1992; Harlow *et al.*, 1992; Rosenblatt *et al.*, 1992; Tzonou *et al.*, 1993; Purdie *et al.*, 1995; Cook *et al.*, 1997; Goddard *et al.*, 1998; Cramer *et al.*, 1999; Gertig *et al.*, 2000; Ness *et al.*, 2000). Upon further review, nine of these met the specified inclusion criteria. Table 1 provides an overview of the nine reports included in the meta-analysis (Hartge *et al.*, 1983; Richardson *et al.*, 1985; Whittemore *et al.*, 1988; Booth *et al.*, 1989; Harlow and Weiss, 1989; Harlow *et al.*, 1992; Rosenblatt *et al.*, 1992; Cook *et al.*, 1997; Ness *et al.*, 2000). A total of 2281 ovarian cancer cases and 3608 controls were enrolled in nine case-control studies. Table 1 also specifies which reports were hospital based versus those that were population based. Only Cook *et al.* (1997) and Harlow and Weiss (1989) used both population-derived cases and controls. All of the other studies listed as 'population based' used hospital-derived cases. The individual study odds ratios listed in Table 1 reflect the odds of exposure in cases versus controls, with an odds ratio greater than one suggesting a positive association, that is, an increased risk of ovarian cancer among women using talc-dusted diaphragms.

Before combining all studies to derive a summary estimate of effect (i.e. a summary relative risk) a statistical test for heterogeneity was performed ( $Q$ ). This gave a value of  $Q$  equal to 10.75. With eight degrees of freedom, the  $P$  value associated with a  $Q$  of this size is 0.22. This indicates that the studies are homogeneous; that is, the studies are measuring an effect of similar

**Table 1 Overview of included studies**

Study (year)	Number of cases/controls	Percentage eligible cases included	Adjusted OR	95% CI	Adjustments to OR	Epithelial tumors only	Borderline tumors incl.	Stratification by histology	H/P
Booth <i>et al.</i> (1989)	235/451	84	0.75	0.85–2.02	Age, SES	Y	Y	N	H
Cook <i>et al.</i> (1997)	313/422	64	0.80	0.40–1.40	Age	Y	N+	Y	P
Cramer <i>et al.</i> (1982)	215/215	72	1.56	0.62–3.88	Parity, menstrual status	Y	Y	Y	P
Harlow <i>et al.</i> (1992)	235/239	59	1.20	0.60–2.40	Parity, education, marital status, religion, use of sanitary napkins, douching, age, weight	Y	Y	Y	P
Harlow and Weiss, 1989	116/158	68	0.50	0.20–1.30	Age, parity, use of oral contraceptives	N/A	All	N/A	P
Hartge <i>et al.</i> (1983)	135/171	69	0.80	0.40–1.40	Age, race, hospital	Y	Unknown	N	H
Ness <i>et al.</i> (2000)	767/1367	61	0.60	0.30–1.20	Age, gravity, race family HX ovarian cancer, oral contraceptive use, tubal ligation, hysterectomy, breast feeding	Y	Y	N	P
Rosenblatt <i>et al.</i> (1992)	77/46	55	3.0	0.80–10.8	Obesity, SES, religion, number of live births, OC use	Y	Unknown	N	H
Whittemore <i>et al.</i> (1988)	188/539	NG	1.5	0.63–3.58	Parity, use of oral contraceptives	Y	Unknown	N	H

SES, socio-economic status; OR, odds ratio; CI, confidence interval; H/P, hospital based/population based; N+, separate analyses done for borderline versus invasive tumors.



magnitudes. Given the lack of statistical heterogeneity, the data were pooled for calculation of a summary relative risk.

Table 1 shows that adjusted odds ratios ranged from 0.60 (Booth *et al.*, 1989) to 3.0 (Rosenblatt *et al.*, 1992), with adjustment parameters specified along with 95% confidence intervals. Of note, none of the reports showed a statistically significant odds ratio. Initial pooling of data from all nine reports yielded a summary relative risk of 1.03 with a 95% confidence interval of 0.80–1.33, a non-statistically significant result suggesting no association between talc/diaphragm use and ovarian cancer risk (see Fig. 1).

Upon closer scrutiny of the available data, further sensitivity analyses were performed as described below. The data provided by Booth *et al.* (1989) did not explicitly provide data on talc use via contraceptive diaphragms and such use could only be assumed. As the data were questionable in this respect they were dropped from the analysis and a summary relative risk was recalculated. The resultant relative risks was 1.12 with a 95% confidence interval of 0.84–1.48. Therefore, the results remained statistically non-significant despite removal of these data from the summary estimate of effect.

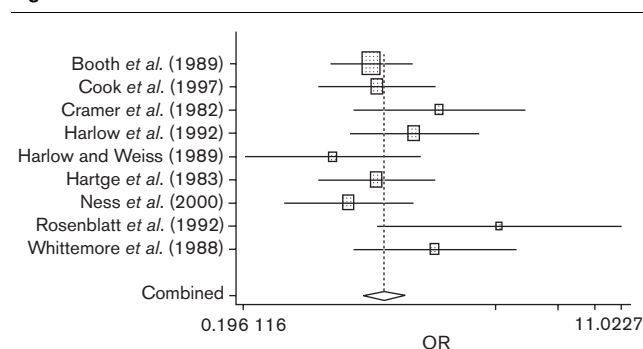
The report by Harlow *et al.* (1992) also represents a potential problem for statistical pooling as the cases in this instance were all patients with ‘borderline ovarian tumors’. The exact nature of borderline ovarian tumors in terms of a relationship with their invasive counterparts remains unclear, with some data suggesting differences in epidemiology and etiology (Riman *et al.*, 2001). Whether borderline tumors are precursors of invasive cancers or a separate disease entity is a matter of debate. We therefore recalculated a summary relative risk without inclusion of data from the study by Ness *et al.* (2000). This gave a

relative risk of 1.09 with a 95% confidence interval of (0.84–1.41), a non-statistically significant result.

All studies except that of Hartge *et al.* (1983) are full research reports with the study by Ness *et al.* (2000) published as a ‘Letter to the editor’. Publication in this format is potentially problematic owing to issues related to the ‘quality’ of the presented data. Letters to the editor normally do not undergo the same type of editorial scrutiny as full research papers. In addition, by their nature, letters are brief notes with limited details presented, precluding rigorous evaluation of methods, results and associated conclusions. In order to address these issues, we dropped the study by Hartge *et al.* from the pooled analysis and, again, recalculated a summary relative risk. This gave a relative risk of 1.07 with a 95% confidence interval of 0.82–1.40. Again, this represents a non-significant finding.

In a prior meta-analysis (Huncharek *et al.*, 2003), we demonstrated a possible bias among studies examining the perineal talc use/ovarian cancer association based on the source of cases. That is, our study suggested that population-based studies may spuriously show a causal association secondary to exposure misclassification to a ‘treatment effect’ among population-derived cases. Some patients with ovarian cancer will undergo treatment with radiation, chemotherapy and/or surgery. Side effects from treatment may prompt talc use among some of these individuals. Patients may not always make the distinction between pre-diagnosis and post-treatment use. Exposure misclassification among ‘prevalent’ cases may cause a spurious finding of an association when none, in fact, exists. We therefore recalculated the summary relative risk excluding the studies by Cook *et al.* (1997) and Harlow and Weiss (1989) as these were the only two reports that utilized population-derived cases and controls. The resultant relative risk was 1.15 with a non-statistically significant odds ratio of 0.87–1.53.

Fig. 1



Forest plot of summary relative risk derived by pooling all available studies using adjusted odds ratios (OR).

Furthermore, this suggests no association between talc use and increased ovarian cancer risk. In fact, if data from the studies by Cook *et al.* (1997) and Harlow and Weiss (1989) are statistically pooled, the summary relative risk is 0.67 with a non-significant confidence interval (i.e. 0.34–1.35). The fact that the population-based relative risk is in the opposite direction (i.e. favoring a protective effect for talc) to that shown in the other case-control studies, further supports the existence of bias in these analyses.

Another methodological consideration is the fact that the definitions of the control groups used across all nine studies are not completely comparable. Some reports defined controls as ‘never having used talc’ (e.g. Ness *et al.*, 2000), while others used controls defined as not



having used talc on diaphragms (e.g. Cook *et al.*, 1997). We therefore calculated crude odds ratios and 95% confidence intervals using data supplied in the available studies and recalculated a summary relative risk to ensure that the analysis using adjusted odds ratio was not spurious (Table 2). The resultant relative risk was 0.86 (0.59–1.40) (see Fig. 2), a non-statistically significant result suggesting no association between talc use on diaphragms and increased ovarian cancer risk (see Fig. 2). Of note, the test for heterogeneity for this latter analysis gave a value for *Q* of 7.20 with a *P* value of 0.52.

Discussion

Talc is an important industrial mineral for a number of reasons including its resistance to heat, electricity and acids and its relatively low price. It is used in many commercial applications because of its lamellar platy nature, softness, whiteness, chemical inertness, high melting point and hydrophobic features, among others. For instance, talc is used in the plastic industry owing to its inertness, superior electrical and thermal resistance and its ability to improve the quality of plastic surfaces. It also finds application in the paint industry to increase the

smoothness of paint products and in paper manufacturing to reduce the usage of expensive whitening agents because of its high brightness.

Mineral talc is a magnesium silicate hydroxide belonging to the mineral class, silicate and subclass phyllosilicate. It belongs to the clay mineral group, an important subgroup within the phyllosilicates that contain large percentages of water trapped between the silicate sheets. Clay minerals are divided into four major groups: the kaolinite group, the montmorillonite/smectite group, the illite group and the chlorite group. Talc is a member of the montmorillon/smectite group along with pyrophyllite, vermiculite, sauconite, saponite and nontronite.

Talc also forms pseudomorphs, that is false shapes, of other minerals, replacing them on an atom by atom basis. For instance, talc forms pseudomorphs of quartz, pyroxene, olivine and amphiboles. In nature, it can also be found in association with a number of other minerals, such as serpentine, quartz, olivine and biotite.

In 1982, Cramer *et al.* (1982) published a case–control study suggesting an association between cosmetic talc use on the perineum and increased ovarian cancer risk. Women dusting the perineum with talc or dusting sanitary napkins showed a near doubling of ovarian cancer risk. Unfortunately, in addition to a number of methodological limitations plaguing this report (e.g. only 45% of eligible controls participating), it is important to point out the flawed premise on which it is based. Cramer *et al.* (1982) cite the ‘chemical relationship between talc and asbestos’ as a major reason for assuming that talc may also be a human carcinogen and that ‘...the mineral talc is a specific hydrous magnesium silicate chemically related to several asbestos group minerals and occurring in nature with them’.

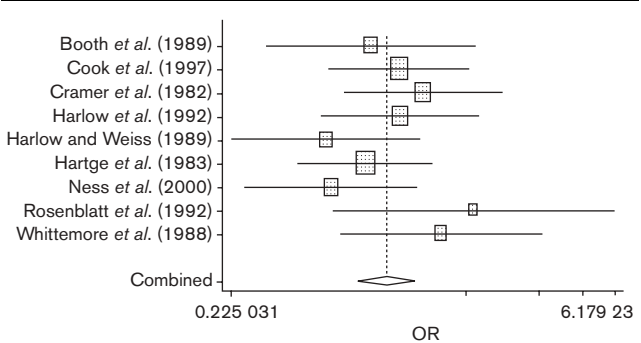
The above-cited justification for the Cramer *et al.* (1982) study and subsequent work examining a possible cosmetic talc/ovarian cancer link is misguided for a number of reasons. Despite the fact that talc and various forms of asbestos are silicates, they are structurally distinct and belong to different mineral groups and subgroups. That is, amphibole minerals (e.g. tremolite) are inosilicates while talc is a member of the silicate subclass phyllosilicate and the group, clay or montmorillonite/smectite. While serpentines, including serpentine asbestos, are also phyllosilicates, serpentine minerals belong to the kaolinite–serpentine group. The asbestos varieties of serpentine are structurally different from other members of the serpentines in that their brucite layers and silicate layers bend into tubes that produce fibers. Non-fibrous serpentine does not have carcinogenic properties and it is clear that the physical structure of serpentine asbestos is responsible for its disease-causing

Table 2 Crude odds ratios and 95% confidence intervals for included studies

Study (year)	Crude OR	95% CI	Variance	Weight
Booth <i>et al.</i> (1989)	0.75	0.33–2.02	0.175	5.70
Cook <i>et al.</i> (1997)	0.96	0.52–1.76	0.097	10.2
Cramer <i>et al.</i> (1982)	1.18	0.59–2.35	0.125	7.99
Harlow <i>et al.</i> (1992)	0.97	0.49–1.92	0.121	8.24
Harlow and Weiss, 1989	0.51	0.22–1.13	0.184	5.43
Hartge <i>et al.</i> (1983)	0.72	0.40–1.30	0.090	11.1
Ness <i>et al.</i> (2000)	0.53	0.25–1.13	0.147	6.80
Rosenblatt <i>et al.</i> (1992)	1.82	0.55–6.34	0.373	2.68
Whittemore <i>et al.</i> (1988)	1.38	0.57–3.28	0.204	4.91

OR, odds ratio; CI, confidence interval.

Fig. 2



Forest plot of summary relative risk derived by pooling all available studies using crude odds ratios (OR).



potential, not its atomic constituents. It simply does not follow, therefore, that one should assume that talc is carcinogenic simply because it is a silicate and a member of the phyllosilicate subgroup. Structure dictates toxicity/carcinogenicity, not chemical composition.

It is true that in nature, mineral talc can be found in association with both serpentine and amphibole minerals, including the asbestos varieties. It is crucial to understand that the carcinogenic potential of asbestos is well known and abundantly documented in the medical and epidemiological literature (Huncharek, 1986; Mossman and Gee, 1989). Cramer *et al.*'s argument suggesting that pure talc is carcinogenic is based solely on 'guilt by association' rather than on scientific fact. If one is exposed to a mixture of talc and asbestos, it is reasonable to expect a carcinogenic effect as it contains a known carcinogen. To then suggest that talc is also carcinogenic simply owing to the fact that it is sometimes found in association with various asbestos minerals in nature is not logical. This reasoning ignores a large body of data regarding the mineralogy of silicates and fails to acknowledge the lack of supporting biological or in-vitro data documenting any carcinogenic potential of pure talc (i.e. uncontaminated by asbestos). A commercial product containing asbestos-contaminated talc could certainly pose a health risk and although prior to the mid-1970s some consumer talc products did, in fact, contain such contamination, the carcinogenic entity is asbestos, not talc (Rohl *et al.*, 1976). It is important to note that since that time, talc product manufacturers voluntarily ensured that such products are asbestos free. Despite this fact, even some recent studies looking at the perineal talc dusting/ovarian cancer risk connection show a weak association (e.g. Mills *et al.*, 2004), further suggesting a spurious finding.

Other evidence that indicates that talc and asbestos have dissimilar biological properties is the fact that talc has been used for decades as a sclerosing agent for both benign and malignant pleural effusions (Viskum *et al.*, 1989). Long-term follow-up studies of these patients have not shown even a single case of lung cancer or mesothelioma resulting from introduction of talc to the pleural cavity (Viskum *et al.*, 1989; Shaw and Agarwal, 2004). Epidemiological studies of talc miners and millers also fail to demonstrate an increased cancer risk (Rubino *et al.*, 1976; Gamble, 1993). In-vivo implantation and injection using asbestos of various types, in contrast, unequivocally induce tumors in experimental animals (Huncharek, 1986).

Despite the above-noted problems, the idea that cosmetic talc poses a possible ovarian cancer risk persists. As reviewed in the present paper and elsewhere (Richardson *et al.*, 1985; Tortolero-Luna and Mitchell,

1995) numerous investigators have examined this possible relationship in a variety of case-control studies and at least one cohort study (e.g. Gertig *et al.*, 2000). Most of these categorized talc use as 'ever versus never' used while others further stratified by particular types of use, for example, perineal dusting, sanitary napkin dusting, condoms, etc. Results differ across studies, with some showing no association (Rosenblatt *et al.*, 1992) while others suggests a 'weak effect' (Purdie *et al.*, 1995), that is odds ratios below 1.5.

In addition to the obvious problems with the premise put forth by Cramer *et al.* (1982) and others, validity of the weak effect shown in a number of other epidemiological studies also remains questionable. The major weaknesses of the existing database include (Boger-Meigiddo and Weiss, 2005) the relatively small sample size of most reports, which limits the statistical power to detect an effect (Richardson *et al.*, 1985), the lack of consistent positive association across studies (Baker and Piver, 1994), the absence of a demonstrable dose-response relationship (Daly and Obrams, 1998), the lack of supporting evidence of talc carcinogenicity from animal or in-vitro analyses (Tortolero-Luna and Mitchell, 1995) and the possible presence of uncontrolled confounding producing a spurious positive association. In fact, some of the available observational studies show an inverse dose-response (Ness *et al.*, 2000) that weighs against a causal association. In addition, no plausible biological mechanism capable of explaining how talc could induce ovarian malignancies exists.

In a study, Heller *et al.* (1996) examined talc particle counts in ovarian specimens from 24 women undergoing incidental oophorectomy and compared these counts with reported frequency and duration of talc use. The study sought to examine the hypothesis of a dose-related risk of epithelial ovarian cancer with perineal talc exposure. Women were considered 'exposed' if they reported talc application to undergarments or directly to the perineum. Talc was detected in all ovaries by either polarized light or electron microscopy. No relationship was found between cosmetic talc burden in healthy ovarian tissue and lifelong perineal talc dusting determined by either microscopic methods. This study raises further questions regarding whether reported associations between perineal talc exposure and ovarian tumors in observational studies reflects a carcinogenic action of talc. The validity of these epidemiologic associations has also been questioned because it is unknown whether talc dust in the perineal area can actually penetrate the female reproductive tract and then translocate to the ovaries against physiological forces working in the opposite direction. The work of Heller *et al.* clearly brings this into question.

Although the epidemiological literature focuses primarily on external perineal exposure to talc, a more valid



assessment of the 'talc hypothesis' would appear to be provided by examining the ovarian cancer risk associated with talc dusting of diaphragms. This particular use of talc results in direct female reproductive tract exposure. Although data on the use of talc-dusted diaphragms have been reported in some epidemiological studies, this literature fails to garner the attention devoted to perineal dusting and no systematic evaluation of this particular literature is available. This probably reflects the fact that perineal dusting is a more common practice than dusting contraceptive diaphragms. Nonetheless, exposure via this latter route is, intuitively, a better 'model' for testing whether talc represents a risk factor for ovarian cancer as the exposure is directly to the female genital tract. Consequently, we performed the above-detailed meta-analysis pooling all available published data on this topic.

Using accepted meta-analytic techniques our analysis was unable to demonstrate any increased risk of ovarian cancer associated with use of talc-dusted diaphragms. Despite performing a number of sensitivity analyses to test the robustness of our findings, the pooled data from over 5000 cases and controls failed to show a positive association. In some studies, the odds ratio was calculated based on an inappropriate control group; for example, individuals who reported no exposure to any talc. For these studies, the crude odds ratio was recalculated based on women who never used talc-dusted diaphragms as the reference group. This summary relative risk was also statistically non-significant.

In summary, our present report, along with our prior meta-analysis pooling data from studies examining the possible ovarian cancer risk associated with perineal talc dusting (Huncharek *et al.*, 2003), does not provide evidence of a causal relationship. In the context of 'weak associations', many sources of bias and uncontrolled confounding can contribute to the finding of a spurious association. Recall bias in case-control studies, lack of a demonstrated dose-response in many published analyses, lack of a coherent biological mechanism for possible talc carcinogenicity and lack of supporting animal or in-vitro data demonstrating the carcinogenic potential of talc all argue against a causal relationship. These limitations and inconsistencies have also been discussed in detail elsewhere (Wehner, 1994; Muscat and Barish, 1998). As ovarian cancer remains a major cause of cancer-related morbidity and mortality in the United States, further work is needed to clearly define modifiable risk factors in an attempt to improve disease prevention.

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# Exhibit 160





WORLD HEALTH ORGANIZATION

INTERNATIONAL AGENCY FOR RESEARCH ON CANCER

**IARC MONOGRAPHS**  
**ON THE**  
**EVALUATION OF THE CARCINOGENIC**  
**RISKS TO HUMANS**

**Overall Evaluations of Carcinogenicity: An Updating  
of *IARC Monographs* Volumes 1 to 42**

*SUPPLEMENT 7*

LYON, FRANCE

1987



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## ASBESTOS\* (Group 1)

### A. Evidence for carcinogenicity to humans (*sufficient*)

Numerous reports from several countries have described cases or series of pleural and peritoneal mesotheliomas in relation to occupational exposure to various types and mixtures of asbestos (including talc containing asbestos), although occupational exposures have not been identified in all cases<sup>1-21</sup>. Mesotheliomas of the tunica vaginalis testis and of the pericardium have been reported in persons occupationally exposed to asbestos<sup>22-24</sup>.

Environmental exposure either in the houses of asbestos workers or in the neighbourhood of asbestos mines or factories has been noted in some of the cases<sup>1,2,4-6,9,11,25,26</sup>. It has been estimated that a third of the mesotheliomas occurring in the USA may be due to nonoccupational exposure<sup>27</sup>. In a study from Israel, the incidence of mesothelioma was found to be higher among those born in the USA or in Europe relative to those born in Israel<sup>9</sup>.

In some of these case reports and in other studies, asbestos fibres were identified in the lung<sup>5,6,11,28-32</sup>. Amphibole fibres usually predominated, but in a few cases mainly or only chrysotile fibres were found<sup>6,28</sup>.

The long latency required for mesothelioma to develop after asbestos exposure has been documented in a number of publications<sup>11,13,26,28,33-37</sup>. An increasing proportion of cases has been seen with increasing duration of exposure<sup>36</sup>.

A number of epidemiological studies of respiratory cancer and mesothelioma have been reported in relation to exposure to unspecified or complex mixtures of asbestos in shipyard work<sup>38-45</sup>. The risk ratio for lung cancer has usually been moderately increased, both in these studies and in studies on various other occupational groups with similarly job-related but unspecified or complex asbestos exposures<sup>35,46-54</sup>. Risk ratios of about 2-5 have been reported in some studies, but the ratio was considerably higher in one rather small study<sup>55</sup> and did not exceed unity in another<sup>42</sup>. In one study, individuals suffering from asbestosis had a considerably greater risk for lung cancer, with a risk ratio of 9.0<sup>56</sup>. In some of the studies referred to, a number of mesotheliomas were also observed<sup>41,42,44,47,51,53,55</sup>. Abdominal mesotheliomas have sometimes been mistaken for pancreatic cancer<sup>57</sup>. Mesothelioma cases have been observed to have a relatively lower fibre content in the lungs than lung cancer cases<sup>32</sup>.

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\* Actinolite, amosite, anthophyllite, chrysotile, crocidolite, tremolite



Laryngeal cancer has been considered in two case-control studies, resulting in risk ratios of 2.4 and 2.3 that relate to shipyard work and unspecified exposure, respectively<sup>40,58</sup>. A cohort study of insulation workers showed a relative risk of 1.9, based on nine cases<sup>57</sup>. A case series indicated a high frequency of exposure to asbestos, especially in low-grade smokers<sup>59</sup>. A risk ratio of 3.2 for laryngeal cancer was reported among chrysotile miners in an area with generally high incidence<sup>60</sup>, but no increased risk was seen in a cohort of workers with exposure to crocidolite<sup>61</sup>. Two correlation studies have also indicated a relationship between laryngeal cancer and exposure to asbestos<sup>39,62</sup>.

Mesotheliomas related to shipyard work and other exposures, including household contact with asbestos workers, have also been subject to epidemiological studies<sup>36,63-67</sup>, resulting in risk ratios of about 3-15 in comparison with background rates not clearly referable to asbestos exposure.

Some studies have specifically considered environmental exposures with reference to mesotheliomas<sup>66,67</sup>. Three correlation studies and one case-control study considering exposure to piped drinking-water<sup>68-71</sup> did not show consistently increased risks for any type of cancer, whereas another study<sup>72</sup> considering chrysotile contamination mainly from natural sources gave some indication of an increase in the incidence of peritoneal and stomach cancers in persons of each sex, although no other cancer site was consistent in this respect.

Exposure to crocidolite has been studied with regard to risk of lung cancer<sup>61,73-76</sup>, and risk ratios of about 2-3 have been reported. Three lung cancers and two mesotheliomas occurred in 20 individuals after one year of high exposure to crocidolite; at least 17 of the cases had asbestos-induced lung changes on X-ray films<sup>77</sup>.

One study<sup>78</sup> of histological types of lung cancers showed that among persons exposed to crocidolite 45.7% of cases were squamous-cell carcinomas, as compared to 35.2% among unexposed persons. In the context of unspecified and complex exposures, small-cell carcinoma was found to be relatively more prevalent than other forms<sup>50</sup>.

Exposure to chrysotile was found in some studies to result in virtually no increase in risk ratio<sup>60,79-81</sup>, or a slightly elevated relative risk of lung cancer<sup>82-86</sup>. Somewhat higher risk ratios, up to 2.5, 3.5 and 2, respectively, were obtained in one study of chrysotile miners<sup>87</sup> and in two independent studies from one asbestos [chrysotile] textile plant<sup>88,89</sup>, the latter being the more comprehensive. With regard to mesotheliomas, one study suggested a particularly high risk of combined exposure to chrysotile and amphiboles (risk ratio, 61), thus almost multiplying the risk ratios (6 and 12, respectively) of exposures to chrysotile and to amphiboles alone<sup>90</sup>. Another study showed no mesothelioma among a large worker population with exposure to chrysotile only<sup>91</sup>.

A slight excess of lung cancer and some mesotheliomas appeared in some groups with mixed exposures involving amosite, chrysotile and crocidolite<sup>92-94</sup>. Exposure predominantly to amosite, but also to chrysotile, was reported to be the probable cause of at least four of five mesotheliomas (one peritoneal) observed in a UK insulation-board factory<sup>95</sup>. One cohort with exposure to cummingtonite-grunerite, which is closely related to amosite, had no clear excess of lung cancer, although one case of mesothelioma was observed<sup>96</sup>.



Exposure to tremolite and actinolite has been the subject of a few studies in investigations of vermiculite mining and milling<sup>97,98</sup> and environmental exposure<sup>99</sup>. The studies of miners indicated a risk ratio for lung cancer of up to approximately six fold. Deaths from mesothelioma were found in the occupational studies, whereas the study of environmental exposure showed no increased risk, although pleural plaques were reported. Publication of one case report of a mesothelioma after environmental exposure suggests that tremolite was of etiological importance<sup>31</sup>.

Cancers other than of the lung or mesothelioma have been considered in many studies<sup>1,17,35,39,41-44,48,51,55,60-62,68-70,72-74,76,83,87,89,92,93,96,97,99-108</sup>. Some indicated an approximately two-fold risk with regard to gastrointestinal cancer in connection with shipyard work<sup>41,43</sup>, and some increased risk was also seen in association with exposure to both chrysotile and crocidolite<sup>103</sup>, to crocidolite<sup>61,74</sup> or to chrysotile<sup>87</sup>. Cancer of the colon and rectum was associated with asbestos exposure during chrysotile production, with an approximately two-fold risk<sup>87</sup>; a similar excess was found for unspecified asbestos exposure<sup>104</sup>. Some excess of ovarian cancer has been reported in two studies<sup>73,76</sup> but not in another<sup>92</sup>; exposure to crocidolite was probably more predominant in the studies that showed excesses. Bile-duct cancer appeared in excess in one study based on record-linking<sup>105</sup>, and large-cell lymphomas of the gastrointestinal tract and oral cavity appeared to be strongly related to asbestos exposure in one small study covering 28 cases and 28 controls, giving a risk ratio of 8; however, ten cases and one control also had a history of malaria<sup>106</sup>. An excess of lymphopoeitic and haematopoeitic malignancies has been reported in plumbers, pipe-fitters, sheet-metal workers and others with asbestos exposure<sup>17,54,107,108</sup>.

The relationship between asbestos exposure and smoking indicates a synergistic effect of smoking with regard to lung cancer<sup>1</sup>. Further evaluations indicate that this synergistic effect is close to a multiplicative model<sup>52,109</sup>. As noted previously<sup>1</sup>, the risk of mesothelioma appears to be independent of smoking<sup>47,66</sup>, and a significantly decreasing trend in risk was observed with the amount smoked in one study<sup>65</sup>.

The studies of the carcinogenic effect of asbestos exposure, including evidence reviewed earlier<sup>1</sup>, show that occupational exposure to chrysotile, amosite and anthophyllite asbestos and to mixtures containing crocidolite results in an increased risk of lung cancer, as does exposure to minerals containing tremolite and actinolite and to tremolitic material mixed with anthophyllite and small amounts of chrysotile. Mesotheliomas have been observed after occupational exposure to crocidolite, amosite, tremolitic material and chrysotile asbestos. Gastrointestinal cancers occurred at an increased incidence in groups occupationally exposed to crocidolite, amosite, chrysotile or mixed fibres containing crocidolite, although not all studies are consistent in this respect. An excess of laryngeal cancer has also been observed in some groups of exposed workers. No clear excess of cancer has been associated with the presence of asbestos fibres in drinking-water. Mesotheliomas have occurred in individuals living in the neighbourhood of asbestos factories and mines and in people living with asbestos workers.



**B. Evidence for carcinogenicity to animals (*sufficient*)**

Asbestos has been tested for carcinogenicity by inhalation in rats, by intrapleural administration in rats and hamsters, by intraperitoneal injection in mice, rats and hamsters and by oral administration in rats and hamsters. Chrysotile, crocidolite, amosite, anthophyllite and tremolite produced mesotheliomas and lung carcinomas in rats after inhalation<sup>1,110,111</sup> and mesotheliomas following intrapleural administration<sup>1,112</sup>. Chrysotile, crocidolite, amosite and anthophyllite induced mesotheliomas in hamsters following intrapleural administration<sup>1</sup>. Intraperitoneal administration of chrysotile, crocidolite and amosite induced peritoneal tumours, including mesotheliomas, in mice<sup>1,113</sup> and rats<sup>1,111,114</sup>. Given by the same route, crocidolite produced abdominal tumours in hamsters<sup>115</sup>, and tremolite and actinolite produced abdominal tumours in rats<sup>110,116-118</sup>. A statistically significant increase in the incidence of malignant tumours was observed in rats given filter material containing chrysotile orally<sup>1</sup>. In more recent studies, tumour incidence was not increased by oral administration of amosite or tremolite in rats<sup>119</sup>, of amosite in hamsters<sup>120,121</sup> or of chrysotile in hamsters<sup>121</sup>. In two studies in rats, oral administration of chrysotile produced a low incidence of benign adenomatous polyps of the large intestine in males (9/250 *versus* 3/254 pooled controls)<sup>122</sup> and of mesenteric haemangiomas (4/22 *versus* 0/47 controls)<sup>123</sup>. Synergistic effects were observed following intratracheal administration of chrysotile and benzo[*a*]pyrene to rats and hamsters<sup>1</sup> and of intratracheal administration of chrysotile and subcutaneous or oral administration of *N*-nitrosodiethylamine to hamsters<sup>124</sup>.

**C. Other relevant data**

Insulation workers exposed to asbestos 'displayed a marginal increase' in the incidence of sister chromatid exchanges in lymphocytes in one study<sup>125</sup>.

Chrysotile did not induce micronuclei in bone-marrow cells of mice or chromosomal aberrations in bone-marrow cells of rhesus monkeys treated *in vivo*. In cultured human cells, conflicting results were reported for the induction of chromosomal aberrations and negative results for the induction of sister chromatid exchanges by chrysotile and crocidolite; amosite and crocidolite did not induce DNA strand breaks, and crocidolite was not mutagenic. Amosite, anthophyllite, chrysotile and crocidolite induced transformation of Syrian hamster embryo cells, chrysotile and crocidolite transformed BALB/c 3T3 mouse cells, and chrysotile transformed rat mesothelial cells. Neither amosite nor crocidolite transformed CH3 10T1/2 cells. In cultured rodent cells, amosite, anthophyllite, chrysotile and crocidolite induced chromosomal aberrations, and amosite, chrysotile and crocidolite induced sister chromatid exchanges; chrysotile and crocidolite induced aneuploidy and micronuclei. Chrysotile induced unscheduled DNA synthesis in rat hepatocytes. Amosite, chrysotile and crocidolite were inactive or weakly active in inducing mutation in rodent cells *in vitro*; none was mutagenic to bacteria<sup>125</sup>.



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# Exhibit 161



## ANALYTIC PERSPECTIVE

## Open Access



# Applying the Bradford Hill criteria in the 21st century: how data integration has changed causal inference in molecular epidemiology

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## Abstract

In 1965, Sir Austin Bradford Hill published nine “viewpoints” to help determine if observed epidemiologic associations are causal. Since then, the “Bradford Hill Criteria” have become the most frequently cited framework for causal inference in epidemiologic studies. However, when Hill published his causal guidelines—just 12 years after the double-helix model for DNA was first suggested and 25 years before the Human Genome Project began—disease causation was understood on a more elementary level than it is today. Advancements in genetics, molecular biology, toxicology, exposure science, and statistics have increased our analytical capabilities for exploring potential cause-and-effect relationships, and have resulted in a greater understanding of the complexity behind human disease onset and progression. These additional tools for causal inference necessitate a re-evaluation of how each Bradford Hill criterion should be interpreted when considering a variety of data types beyond classic epidemiology studies. Herein, we explore the implications of data integration on the interpretation and application of the criteria. Using examples of recently discovered exposure–response associations in human disease, we discuss novel ways by which researchers can apply and interpret the Bradford Hill criteria when considering data gathered using modern molecular techniques, such as epigenetics, biomarkers, mechanistic toxicology, and genotoxicology.

**Keywords:** Causation, Causal inference, Data integration, Bradford Hill, Molecular epidemiology

## Background

In 1965, Sir Austin Bradford Hill gave the first President’s Address to the newly formed Section on Occupational Medicine, which was published within the Proceedings of the Royal Society of Medicine [1]. Hill began his address by pointing out a fundamental problem facing the Section members: how could they effectively practice preventative occupational medicine without a basis for determining which occupational hazards ultimately cause sickness and injury? Namely, Hill asked, “In what circumstances can [one] pass from [an] observed *association* to a verdict of *causation*?” [1]. He proceeded to propose nine “aspects of association” for evaluating traditional epidemiologic data. These aspects, which have since become fundamental

tenets of causal inference in epidemiology, are often referred to as the Bradford Hill Criteria.

The nine “aspects of association” that Hill discussed in his address (strength of association, consistency, specificity, temporality, biological gradient, plausibility, coherence, experiment, and analogy) have been used to evaluate countless hypothesized relationships between occupational and environmental exposures and disease outcomes. Yet, when Hill conceived these nine aspects (hereafter referred to as criteria), the mechanistic connections between exposure and disease were not well understood. Consider that Hill published his criteria just 12 years after Watson and Crick first suggested the double-helix model for DNA. Traditional epidemiologic study designs that were developed and used around the time of Hill’s speech treated the connection between exposure and disease as a ‘black box’—meaning that the biological mechanisms that occur between exposure and disease onset were unknown and therefore omitted in

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study design [2]. Over the past 50 years, advances in scientific fields (e.g., molecular genetics, genomics, molecular toxicology) and technology (e.g., computers, software, statistics, analytical methods) have provided researchers with a much deeper and more complex understanding of how diseases initiate and progress, effectively allowing researchers to glimpse into the ‘black box’ of the exposure-to-disease paradigm. As a result, researchers considering causal inference have new and more diverse types of information to consider when establishing causality beyond the traditional epidemiologic study designs that were available when Hill wrote his causal criteria.

Data integration refers to the incorporation of data, knowledge, or reasoning from across multiple disciplines or approaches, with the goal of generating a level of understanding or knowledge that no discipline achieved alone [3, 4]. Data integration, while not always referred to by that term, has been discussed in light of causal inference of disease for over a decade, and the epidemiologic community has generally welcomed these interdisciplinary collaborations [5–7]. For example, the preface of the 5th edition of the *Dictionary of Epidemiology* directly acknowledges the “positive blurring of the boundaries of epidemiological research methods” into other scientific disciplines. The preface welcomes non-epidemiologists to contribute to and use the *Dictionary* and inversely invites trained epidemiologists to utilize the concepts within the *Dictionary* in non-epidemiological initiatives [4]. Furthermore, numerous agencies, organizations, and academics have recently attempted to establish frameworks or guidelines for data integration in the field of human health and ecological risk assessment. These frameworks consider how researchers should address, compare, and contrast the value and contributions of data that come from different evidence streams or scientific disciplines [8–11].

Hill aptly stated at the end of his speech that “[a]ll scientific work is incomplete... [and] liable to be upset or modified by advancing knowledge” [1]. Today, researchers considering causal inference must integrate data from a variety of scientific disciplines. Herein, we discuss how data integration in the field of causal inference of diseases affects the application and interpretation of each of Hill’s criteria.

### Criteria 1: strength of association

Hill’s first criterion for causation is *strength of the association*. As he explained, the larger an association between exposure and disease, the more likely it is to be causal. To illustrate this point, Hill provided the classic example of Percival Pott’s examination of scrotal cancer incidence in chimney sweeps. The tremendous strength of association between that occupation and disease—nearly 200 times

greater than seen in other occupations—led to a determination that the chimney soot was likely a causal factor. Contrarily, Hill suggested that small associations could more conceivably be attributed to other underlying contributors (i.e. bias or confounding) and, therefore, are less indicative of causation.

Defining what constitutes a “strong” association is critical to the assessment of potentially causal relationships. Advances in statistical theory and the computational processing power have allowed scientists to delineate strong versus weak associations using more defensible mathematical criteria than Hill had in mind. Strength is no longer interpreted as simply the magnitude of an association. Furthermore, researchers have gained a greater appreciation for multi-factorial diseases and the existence of determinant risk factors that are small in magnitude yet statistically strong. Today, statistical significance—not the magnitude of association—is the accepted benchmark for judging the strength of an observed association, and thus its potential causality.

Yet, these same statistical and computational advances necessitate an added degree of scrutiny when interpreting study results. Modern tools have enabled researchers to collect much larger datasets, access wide ranges of metadata, employ complex algorithms, and choose from a multitude of statistical approaches. As such, statistically significant results presented within a study are not always biologically meaningful or methodologically appropriate for contributing to causal inference. Conversely, failure to mathematically demonstrate statistical significance in a single study does not preclude the possibility of a meaningful exposure–response relationship in reality. Thus, assessing *strength of association* in causal inference requires examination of underlying methods, comparison to the weight of evidence in the literature, and consideration of other contextual factors including the other criteria discussed herein.

An example can be seen in the analysis and subsequent re-analysis of pulmonary function in a cohort of 106 workers at a flavorings manufacturing facility that used a variety of chemicals, including acetaldehyde, acetoin, benzaldehyde, butyric acid, and diacetyl [12, 13]. In the original study conducted by the National Institute for Occupational Safety and Health (NIOSH), researchers retrospectively analyzed spirometry reports and job title records collected by the cohort’s employer [13]. The authors presented statistically significant effect estimates showing that employees in jobs with higher potential for flavoring chemical exposures had 2.8 times greater annual declines in forced expiratory volume (FEV) than employees in lower-exposure jobs. This led authors to conclude that there was a statistically strong association between occupational exposure to flavorings and



restrictive pulmonary disease [13]. However, as Ronk et al. [12] pointed out, the NIOSH researchers did not account for the inherently correlated nature of the longitudinal spirometry test data in their choice of regression analysis, which would affect the data variability and therefore standard error estimates and subsequent statistical inference [14, 15]. Ronk and colleagues re-analyzed the same data set using generalized estimating equations (GEE) that account for these correlations and did not find any statistically significant associations [12]. The varied outcomes and author interpretations associated with these two studies underscores how the use of different statistical methods can lead to statistically different results, thus impacting the application of *strength of association*.

### Criteria 2: consistency

Traditionally, Hill's *consistency* criterion is upheld when multiple epidemiologic studies using a variety of locations, populations, and methods show a consistent association between two variables with respect to the null hypothesis. Hill stressed the importance of repetitive findings because a single study, no matter how statistically sound, cannot be relied upon to prove causation due to ever-present threats to internal validity. This criterion is still very appropriate for determining causal relationships; however, data integration practices have led to an evolution in thought on what constitutes consistency. The concept of data integration is inherently influential in the interpretation of the *consistency* criterion as it speaks to understanding a consistent story across multiple disciplines or practices. For example, through the lens of data integration, molecular experimentation can bolster epidemiologic findings by providing supportive evidence for a mechanistic hypothesis, thereby lessening the need for repetition among numerous observational studies. In vitro toxicology studies that suggest a mode of action such as genotoxicity or altered gene expression can support an association found in an epidemiologic study. By integrating results from multiple types of studies, researchers can show consistency in the causal story by illuminating various mechanistic points along the exposure-to-effects paradigm. This is a much broader interpretation of *consistency* than Hill's original concept of repetitive epidemiologic findings.

The story of benzene-associated Acute Myeloid Leukemia (AML) illustrates the application of the *consistency* criterion in light of modern data integration. Both animal models and in vitro human cell cultures demonstrated that hydroquinone and para-benzoquinone are the active metabolites of benzene [15, 16]. Additionally, it was shown that hydroquinone induces cell changes that are consistent with various cellular changes known to

mark the early progression of AML in humans [16, 17]. These molecular-level studies supported available human in vivo data (i.e., standard epidemiological studies), thereby lessening the need for additional observational studies to support a causal relationship.

Similarly, data integration played a role in the demonstration of consistency to support a causal relationship between polychlorinated biphenyl (PCB) exposure and melanoma. Consistency among epidemiologic studies of PCB exposure and melanoma, and in vitro mechanistic studies with human melanocytes support a plausible mechanism by which PCBs disrupt melanogenesis [18, 19]. Collectively, these data contributed to the decision by the International Agency for Research on Cancer Monograph Working Group to upgrade PCBs to a Group 1 carcinogen [18, 20]. Consistency between rodent and human bioassays also demonstrates support for a mechanism of carcinogenicity via initial binding to the aryl-hydrocarbon receptor (AhR) by PCB 126 and 2,3,7,8-tetrachlorodibenzo-para-dioxin, (TCDD) in other cancers [18, 20]. These examples illustrate how advanced molecular analyses can be integrated with the results of observational studies to demonstrate consistent research findings supporting a potentially causal relationship.

### Criteria 3: specificity

Hill suggested that associations are more likely to be causal when they are specific, meaning the exposure causes only one disease. While Hill understood that some diseases had multiple causes or risk factors, he suggested that "if we knew all the answers we might get back to a single factor" responsible for causation. This view is indicative of the fact that, in Hill's era, exposure was often defined in terms of proxies for true exposures, such as an occupational setting or a residential location. Today, we attempt to specifically define exposures not in terms of a person's surroundings or conditions, but rather as an actual dose of a chemical, physical, or biological agent. While some examples of highly specific agent-outcome associations exist, most exposure and health concerns at the forefront of research today center around complex chemical mixtures and low-dose environmental and occupational exposures complicated by a variety of risk factors.

The original criterion of *specificity* is widely considered weak or irrelevant from an epidemiologic standpoint. However, *specificity* may have new and interesting implications in the broader context of data integration. For example, researchers can demonstrate a molecular mechanism of action with precisely defined (i.e., specific) relationships between the agent and the effects using a variety of research methodologies. Asbestos exposure and the development of asbestosis is one example. In



addition to the common use of occupational history as a surrogate for asbestos exposure in an epidemiological framework, advances such as refined standardized criteria for clinical diagnosis of asbestosis, microscopic lung fiber burden analyses and identification of asbestos bodies, as well as increased understanding of the relative potency of different fiber types have further clarified how asbestosis may be specifically caused by asbestos exposures [21–24]. With data integration, *specificity* evolves into a more powerful criterion, and the lack of specificity can help to narrow down specific agents associated with disease. For example, complex mixtures of chemicals (e.g., tobacco smoke) typically lack specificity when studied using classic epidemiology designs, since multiple diseases can result from the exposures. However, it is possible that data integration may elucidate some mechanistic specificity among the varied disease endpoints associated with these complex carcinogenic mixtures.

#### Criteria 4: temporality

*Temporality* is perhaps the only criterion which epidemiologists universally agree is essential to causal inference. Consider that Rothman and Greenland, despite finding a lack of utility or practicality in any of the other criteria, referred to *temporality* as “inarguable” [25]. Hill explained that for an exposure-disease relationship to be causal, exposure must precede the onset of disease. Thus, epidemiologic study designs which ensure a temporal progression between the two measures are more persuasive in causal inference.

When ensuring temporality in the context of modern-day environmental exposures, it is important to consider that many of these involve low levels of exposure over extended time frames, and low incidence, micro-scale outcomes that occur following long latency periods. These factors make the prospect of designing a traditional epidemiologic study in which temporality is firmly established a costly, time consuming, and potentially unfeasible task. However, improved chemical exposure monitoring and analytical capabilities, molecular epidemiology techniques, and advances in understanding disease progression allow for new and expanded ways to meet this criterion across a variety of study designs. The use of biomarkers, state-of-the-art analytical testing at low limits of detection, and understanding of windows of toxicity and chromosome abnormalities in disease progression have increased our confidence in *temporality* as a useful criterion.

A modern example of expanded temporal analysis using data integration is illustrated by studies of low-dose exposures to arsenic through drinking water and food. Arsenic levels in hair and nails serves as a biomarker of past exposure [26, 27], and drinking water analytical

records from an individual's past and present residences can be used to create an estimate of historic environmental exposure [28]. Limited windows of exposure can be evaluated to determine effects of exposure during sensitive stages [29, 30]. By integrating new data and knowledge from these tools, temporal relationships can be considered even within cross-sectional or ecological studies that do not implicitly establish temporality within the study design.

Today, our understanding of temporality now includes a wider range of precisely defined wider exposure windows, some of which are more relevant to disease outcomes than previously thought. Through epigenetic mechanisms (i.e., DNA methylation, histone modifications), exposures that occur during specific periods of development or even in previous generations can result in phenotypic differences in offspring [31]. Such changes could be responsible for generational effects of synthetic estrogen diethylstilbestrol (DES) exposure which can lead to increased risk of breast cancer multiple generations removed from the initial exposure [32]. Analytical techniques are improving to detect these changes and to determine which epigenetic alterations may serve as indicators of disease potential and persistent biomarkers of a previous exposure [33]. Understanding the molecular-level changes that precede an observable outcome can help establish the temporal progression in a multigenerational causal story [34].

#### Criteria 5: biological gradient

Hill wrote that “if a dose response is seen, it is more likely that the association is causal.” According to the traditional interpretation of *biological gradient*, the presence of a dose–response relationship supports the causal association between an exposure and an effect [25, 35]. In traditional epidemiology, a monotonic biological gradient, wherein increased exposure resulted in increased incidence of disease, provides the clearest evidence of a causal relationship. However, Hill acknowledged that more complex dose–response relationships may exist, and modern studies have confirmed that a monotonic dose–response curve is an overly simplistic representation of most causal relationships. In fact, most dose–response curves are non-linear and can even vary in shape from one study to the next depending on unique characteristics of the given population, exposure routes, and molecular endpoints assessed [36]. Furthermore, individual susceptibility and synergistic or antagonistic effects of cumulative exposures can make some biological gradients even more difficult to characterize. An example of this effect can be seen in aryl hydrocarbon receptor (AhR)-based mechanisms: many exogenous and endogenous agents can act as partial agonists/antagonists



of AhR, and thus modulate the dose–response effect of 2,3,7,8-tetrachlorodibenzodioxin (TCDD) which affects gene expression via AhR [9]. Integration of advanced statistical capabilities, data modeling techniques, and knowledge from increased understanding of biomolecular interactions have resulted in the descriptions of more defined dose–response curves, capable of showing molecular effects at very low levels of exposure. Additionally, growing knowledge of genetic polymorphisms has illuminated the reasons behind individual variations in biological response to toxic insult and the dose–response relationships [8].

It is now possible to observe threshold responses in the low-dose range, rather than assuming linearity for all substances. Furthermore, experimental support for a dose–response phenomenon referred to as hormesis has increased with improved molecular techniques. Hormesis is characterized by low dose stimulation and a high dose inhibition [37]. The dose–response curve associated with this phenomenon is biphasic and, depending on the endpoint measured, is either J or U shaped [38]. Hormesis has been observed in both toxicology and pharmacology, and the features of the observed dose–response are consistent and independent of the biological model, endpoint measured, chemical or physical stressor, and mechanism [37]. The most distinctive feature of hormesis is that it is repeatedly observed below the typical threshold dose [37].

*Biological gradient* is an example of how data integration can complicate causal inference. New tools and technical capabilities have allowed researchers to characterize a variety of low-level molecular endpoints that may not lead to disease or observable adverse outcomes on a larger scale. For example, innate responses can repair, eliminate, or reverse molecular changes caused by low levels of exposure. Thus, molecular changes within the no-observable-adverse-effect level (NOAEL) may not contribute to disease and are more indicative of a threshold dose response. Understanding the mechanisms at low level exposures allows us to elucidate a dose–response curve. For example, the in vitro endpoints for asbestos toxicity include generation of oxidative stress which results in genotoxicity and chromosome damage via DNA adduct formation [39]. However, damage at low levels, while measurable in vitro, is removed via cellular apoptosis which represents adaptive response and a threshold effect. Thus, responses at these low levels may not be indicative of disease, but rather adaptive responses that indicate a threshold must be overcome prior to disease initiation.

Additionally, modern analytics have shown that epigenetic endpoints can occur in the low-dose range of environmental chemical exposures, though these measured

changes may not lead to observable disease. For example, Kim et al. [40] observed non-monotonic dose-dependent alterations in DNA methylation among mouse liver samples from offspring exposed perinatally to multiple doses of BPA through the maternal diet. These changes may provide insight regarding a mechanism of action for BPA during developmental exposure; however, further information regarding phenotypic changes is necessary to determine whether epigenetic changes at low level exposures are significant indicators of a dose–disease response relationship. Thus, *biological gradient* can be broadened to include molecular dose–response relationships, if the actual response occurs at a dose that is also associated with disease onset or progression.

### Criteria 6: plausibility

Even at the time it was introduced, *biological plausibility* represented fundamental concepts of data integration—the criterion implies that epidemiology and biology must interact [5]. Plausibility has historically been judged based on the presence of existing biological or social models that explain the association of interest. Hill's criterion of plausibility is satisfied if the relationship is consistent with the current body of knowledge regarding the etiology and mechanism of disease; though, Hill admitted that this interpretation of *biological plausibility* was dependent on the current state of knowledge. Today, tools such as high-throughput screening assays can be used to study a specific biologically plausible pathway and identify toxic agents that interfere with that pathway in defined ways. Indeed, opening the 'black box' through integrating molecular epidemiological advancements has allowed researchers to illuminate more steps in the exposure-to-effect paradigm, contributing to an understanding of biological plausibility for suggested causal relationships.

The elucidation of biological pathways leading to liver toxicity have played a large role in advancing the interpretation of *biological plausibility*, and the integration of knowledge from various evidence streams has aided in those interpretations. The liver is typically the first organ with appreciable capacity for oxidative metabolism that an agent encounters after ingestion, and is therefore a key organ for studying potential toxicity [16]. Liver effects demonstrated using techniques such as high-throughput in vitro and in silico cell manipulation, can be seen as a harbinger for further toxic endpoints that might occur with more refined, realistic exposures [41, 42]. However, as demonstrated by the newly-developed "virtual liver" [43], the future of testing biological plausibility likely lies with in silico experimentation. Researchers can now predict plausible relationships using in vitro and in silico screening tools targeting defined disease mechanisms,



which represents a potential paradigm shift in how scientists frame causal research questions and design studies.

Historically, causal inference was approached with the assumption of a single-factor direct relationship (i.e. A causes B). However, researchers now understand that many disease outcomes are a result of the interplay and balance between multiple contributing and intermediary factors. As such, demonstrating the biological plausibility of a causal relationship can be complex. However, improved statistical techniques can help researchers to understand complex disease progression from a molecular standpoint, where multiple risk factors, confounders, adaptive responses, and mediating mechanisms intersect [44–46]. For example, the biostatistical approach of mediation analysis allows for the disentanglement and decomposition of the various biological pathways of direct and indirect effects that play a role in filling the “black box” between exposures and observable outcomes [47].

### Criteria 7: coherence

*Coherence* has been viewed as being similar to *biological plausibility*, in that the cause-and-effect story should make sense with all knowledge available to the researcher, and this criterion has not changed greatly since its inception. Indeed, Hill identified histopathological evidence of bronchial epithelium changes and animal-based toxicity tests for the carcinogenicity of cigarette smoke as an example of a coherent story among several avenues of study design. Today, *coherence* is another area in which molecular-based studies have been used to demonstrate a comprehensible story regarding various aspects of the exposure-to-disease paradigm. For example, lung tissue fiber analysis by scanning transmission electron microscopy (STEM) has expanded our knowledge of internal biologically effective amphibole dose relating to altered structure and function of lung tissue, supporting the conclusion that amphibole asbestos fibers induce mesothelioma [48].

Alternatively, advanced mechanistic studies can elucidate an incoherent body of epidemiologic literature, thereby strengthening the causal inference in one direction or another. Consider for example the carcinogenicity of hexavalent chromium [Cr(VI)]. The body of epidemiologic literature regarding the carcinogenicity of Cr(VI) is limited and conflicting, particularly regarding ingestion exposures (e.g., drinking water) and cancers outside the respiratory system (e.g., cancers of the GI tract). However, a recent array of genomic, pharmacokinetic, and mechanistic research—including metabolism, bioavailability and kinetic studies, mutagenic mode of action studies, and gene expression profiling—demonstrate that ingested Cr(VI) does indeed have a carcinogenic profile [49, 50].

### Criteria 8: experiment

Hill explained that evidence drawn from experimental manipulation—particularly epidemiologic studies in disease risk declines following an intervention or cessation of exposure—may lead to the strongest support for causal inference. Yet in modern contexts, experimentation must consider that many diseases result from multifaceted exposures and follow complex progression pathways. Cessation of exposure as Hill described may not reverse or appreciably slow the progression of disease. In some cases, multiple risk factors, including diet, exercise, smoking, chemical exposures, and genetic predisposition can contribute to disease onset and progression. Thus, while the combination of these factors may culminate in disease, experimental manipulation of a single contributory factor may or may not result in observable decreases in disease incidence.

Researchers using a data integration framework can now draw from toxicological findings for experimental insight into causality. In vitro studies that test mechanistic pathways and demonstrate the biological role of an agent in disease progression may result in knowledge that can be used to predict potential human health outcomes in a much more time-efficient manner than human studies, particularly for adverse outcomes with a long latency period.

The expanded understanding of *temporality* in light of data from varied evidence streams can also affect interpretation of the *experiment* criterion. Individual exposures can cause epigenetic modifications to parental DNA that result in an observed effect in future offspring, even though there is no direct exposure to the offspring. Experimental studies in animal models are often necessary to provide mechanistic support for an epidemiologic observation that involves complex temporality. For example, multiple animal studies provide support for the hypothesis that epigenetic changes induced by DES exposure in utero may be causative of transgenerational effects of DES exposure in females [32, 51–54]. Because epigenetic analyses in transgenerational human studies take decades and are riddled with potential confounders, reliance on animal models and advanced analytical techniques can help to support determination of a causal relationship.

### Criteria 9: analogy

Hill implied that when there is strong evidence of a causal relationship between a particular agent and a specific disease, researchers should be more accepting of weaker evidence that a similar agent may cause a similar disease. *Analogy* has been interpreted to mean that when one causal agent is known, the standards of evidence are lowered for a second causal agent that is similar in some



way [55]. Some modern epidemiologists have argued that a lack of analogy does not preclude causation, but simply implies a lack of creativity on the researcher's part [56]. Indeed, some might argue that enough knowledge exists and is accessible today to identify an analogy for every situation, especially if the researcher pulls that knowledge from multiple disciplines and across evidence streams. Today, researchers have a wider range of tools by which to seek an analogy, including disease progression pattern, common risk factors and confounders, and biological mechanisms of action. Therefore, the modern value of *analogy* is not gained from confirming a causal inference, but rather from proposing and testing mechanistic hypotheses.

As an example, analogous mechanistic hypothesis testing has been conducted on carbon nanotubes (CNTs) using the extensive literature on the mechanistic toxicity of asbestos fibers. Models based on molecular structure and physical–chemical characteristics such as aspect ratio predict a mechanism of action similar to that of asbestos [57]. The physical morphology of CNTs appears similar to that of asbestos fibers; thus, respirable-sized fibers are expected to behave similarly in occupational settings and lead to similar lung translocation and deposition. Additionally, asbestos fibers are known to cause inflammation and fibrosis of the lung pleura as a precursor to mesothelioma; these same outcomes have been demonstrated following CNT exposure [58, 59]. Further, CNTs have been found to stimulate the release of acute phase cytokines from human macrophages and mesothelial cells exposed to CNTs of varying lengths, demonstrating that CNT exposure results in a length-dependent pro-inflammatory response, similar to that of asbestos [60]. These findings enhance the asbestos analogy by confirming that CNTs may be capable of causing disease that begins with pleural inflammation—the same mechanism responsible for asbestos-related mesothelioma. However, the results also demonstrate that not all CNTs have the same potential for carcinogenicity, implying that proactive design of engineered CNTs can limit the risks and allow for safe use of the compounds in a variety of applications—and that the analogy to asbestos should not be viewed in a way that limits continued research.

## Conclusion

Hill's nine aspects of association were never intended to be viewed as rigid criteria or as a checklist for causation, yet have been popularized as such over the past 50 years. Instead, the so called "Bradford Hill Criteria" were written as flexible guidelines or considerations meant to guide epidemiologic investigations and aid in causal inference. As the world of epidemiologic research has changed and expanded, our criteria for determining

causal inference must similarly evolve. As Chen and Hunter explained, researchers today are "much more of a participant in the assessment of the biologic basis for an association, by using biologic measurements to assess exposure, internal dose, biologically effective dose, early biologic effect, altered structure/function, invasive cancer diagnosis, tumor metastasis and prognosis"—essentially, the 'black box' between exposure and disease can now be peered into and explored [2]. Epidemiologic investigation of causation conducted today must also evolve to reflect the concepts of data integration. This involves incorporating not just traditional epidemiological evidence but also evidence gathered by opening the 'black box' and incorporating data from molecular biology, toxicology, genotoxicology, and other disciplines into evaluations of causation. The advanced tools and techniques that have developed in recent decades across all scientific disciplines have affected the application and interpretation of the Bradford Hill criteria, which were originally written to fit the 'black box' model of epidemiologic studies.

The Bradford Hill Criteria remain one of the most cited concepts in health research and are still upheld as valid tools for aiding causal inference [61]. However, the way each criterion should be applied, interpreted, and weighted in a data integration framework must be carefully measured against the varied and often novel types of data available in each unique situation. In some ways, data integration degrades the value and importance of certain criteria, as it offers alternative interpretations for each criterion that give way for inductivism. In other words, in a data integration framework, researchers can interpret the criterion whichever way fits the available data as opposed to determining whether the data meets the criterion. This type of application is dangerous as it bypasses the ultimate purpose of causal inference—determining whether the observed association is directionally causal or not.

Nonetheless, data integration represents an opportunity to expand our abilities as researchers to think about causation. Herein, we have discussed how the data integration framework requires the compilation of more lines of evidence and more scrutiny for each of the criteria. The examples above have demonstrated that data integration can enhance the application of the Bradford Hill Criteria in a causal analysis by: allowing for more scrutiny in study designs; providing new tools to demonstrate consistency, specificity, and plausibility of associations; integrating molecular evaluation to determine temporality and dose–response; clarifying conflicting epidemiologic findings to determine coherence; and promoting the proposal and testing of new mechanistic hypotheses.

The Bradford Hill Criteria are far from outdated in a data integration framework. Causal inference in the field



of epidemiology is no longer informed solely by traditional epidemiologic studies, but rather by a complementary host of evolving research tools and scientific disciplines. Although specific interpretations of each criterion have evolved over time, the concepts that underlie each criterion can be applied to a variety of methodologies to answer questions about causation. The Bradford Hill Criteria can aid researchers in connecting the dots within a body of literature, either to lead to suggestions of causal relationships or identification of what more research is needed to understand potential causality. As ever, the criteria should not be used as a heuristic for assessing causation in a vacuum; rather they should be viewed as a list of possible considerations meant to generate thoughtful discourse among researchers from diverse scientific fields. The interpretive concepts we have introduced into each Bradford Hill criterion in light of data integration support the Bradford Hill Criteria's function as a valid and useful tool when establishing causation.

#### Authors' contributions

All four authors contributed to thematic development, literature-based research, and writing. All authors read and approved the final manuscript.

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# Exhibit 162





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# Weight of Evidence: General Principles and Current Applications at Health Canada

**PREPARED FOR:** Task Force on Scientific Risk Assessment

**PREPARED BY:** Weight of Evidence Working Group



**Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health.** Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

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1	November 2011		Initial issuance of final document.
2	May 2018	Document Revision History	Section added to track revisions.
		Annex 2	Program areas, interpretations and applications updated.
		8.0 References	Section 8.0 added; Reference list updated throughout document.

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# 1. Introduction

Weight of Evidence (WoE) is frequently cited as the basis on which risk assessment conclusions are made. However, multiple interpretations and a lack of consensus about its meaning could potentially compromise communication between diverse stakeholders in the decision-making process. In response to this issue, an analysis of the WoE approach was initiated by Health Canada's Science Policy Directorate in 2010, as a project under the Task Force on Scientific Risk Assessment. By examining current interpretations and identifying potential best practices, this analysis aims to enhance the consistency and coherence of risk assessments across the Department.

## 2. Purpose and scope

The current document aims to inform senior management about WoE in Health Canada risk assessments by providing an overview of the approach in terms of its:

- role in scientific risk assessments;
- main guiding principles; and
- application by various risk assessment programs at Health Canada.

In addition, this explanatory document serves as a value-added Departmental resource of high level contextual information and guiding principles to supplement program specific guidelines, procedures and/or tools.

While this document acknowledges that WoE could also be applied in the risk management decision making context, where scientific evidence is weighed against other policy considerations, it will not expand on this information as it is considered **not** within the scope of this document.<sup>9</sup>

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<sup>9</sup> The terms evidence, information and data are used interchangeably in this document, and refer to general scientific usage, not specific legal definitions of what constitutes evidence, or "admissible" evidence, in a court of law.



### 3. Role in risk assessments

In general, scientific risk assessments encompass the following steps: identifying and characterizing the hazard, assessing the exposure, and characterizing the risk; risk assessments also play an integrated role in an evidence- informed decision making process which also involves managing and communicating the risk.

WoE in the risk assessment context is defined in *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks* (Health Canada, 2000) as:

*“A qualitative measure that takes into account the nature and quality of scientific studies intended to examine the risk of an agent. Uncertainties that result from the incompleteness and unavailability of scientific data frequently require scientists to make inferences, assumptions, and judgements in order to characterize a risk. Making judgements about risk based on scientific information is called “evaluating the weight of evidence”.*

The above description can be interpreted to implicitly include two separate concepts frequently associated with WoE terminology:

1. **Totality of Evidence:** what types and sources of information are to be gathered and considered for subsequent assessment; and
2. **Weighing Evidence:** how such individual sources of evidence are assessed and integrated into an overall conclusion or recommendation.

Totality of evidence can be influenced by varying interpretations of “all” available or relevant evidence to date. This concept provides the opportunity to make use of information/studies that may be regarded insufficient individually, but which contribute to a total “weight of evidence” case in support of conclusions during risk assessment when they are considered alongside other studies/sources of evidence. Moreover, an evaluation of evidence and of any subsequent decision can be reassessed, at a later date, based on the availability of data that may not have been readily available at the time of the original assessment.

The latter, methodological concept of weighing evidence is applicable to most risk assessments. While specific methodologies and tools used for assessing and integrating evidence (e.g., quantitative or qualitative) may vary and are context dependent, the general principles for the assessment and integration process remain the same.



## 4. General principles

The inter-relationship of the above two concepts, and the general principles of the WoE approach outlined below, is presented in Annex 1, for illustrative purposes only. The Totality of Evidence concept includes the general principles 4.1, 4.2, and 4.3, while the methodological concept of Weighing Evidence can be subdivided into the general principles of 4.4 and 4.5. Regardless of specific interpretations of terminology, the following steps are applicable to building a “weight of evidence” case for a given risk assessment conclusion or recommendation.

### 4.1 GATHERING “ALL” AVAILABLE EVIDENCE

Multiple sources and types of evidence may be gathered or submitted and considered in context of “all” available evidence to date. Depending on the regulatory data requirements, the full spectrum of sources and types of evidence may include: randomized controlled clinical trials, company and/or third party generated studies of a proprietary nature, peer-reviewed, published scientific literature, expert opinion reports, decisions and analysis reports from regulatory authorities, incident reports, adverse reactions submitted to regulatory authorities, and unpublished data.

### 4.2 ASSESS INDIVIDUAL STUDIES

General criteria for inclusion/exclusion are useful when screening “all” evidence gathered for further consideration. While specific terminology and scope for inter-related screening criteria such as “quality”, “reliability”, “relevance”, etc. could differ across various regulatory programs and agencies, the underlying principles are common. Assessment could involve use of specific scoring tools and/or best professional judgement. Acceptable studies that meet standards for inclusion are assessed further in subsequent steps of the WoE approach, while unacceptable studies may be excluded from further consideration. For example, unpublished data, or data irrelevant to the risk assessment endpoint in question, may be excluded from further consideration or may be given a lower weight when assembling the lines of evidence. When necessary, the rationale for including (or excluding) studies could be documented in the relevant report.



### 4.3 ASSEMBLING LINES OF EVIDENCE

The types and sources of evidence considered are diverse and vary considerably in level of detail. Depending on the context of the risk assessment in question, individual studies or data sources are often assessed as distinct lines of evidence on their own, or considered in concert with other similar studies that together constitute a particular “line of evidence”. Such lines can be organized according to unifying characteristics, such as source or type of data (e.g., animal data, human data, clinical trials, and literature data). Separate lines of evidence can also be drawn along sub-components of risk, such as hazard, exposure, human health, environmental safety, or other characteristics such as studies which support or counter a particular conclusion. These lines can be further subdivided into more specific lines. For example, “hazard” can be divided into specific organ systems (hazard to the liver, kidneys, brain, etc.).

### 4.4 ASSESSING LINES OF EVIDENCE

Lines of evidence are assessed against various criteria that are dependent on the context of the particular endpoint in question. Risk assessments can be hypothesis driven, and designed to answer yes/no questions (e.g., is substance x a carcinogen?). In such instances, several lines of evidence (e.g., carcinogenicity studies, genotoxicity studies, or mechanistic data) can each be assessed based on criteria such as the strength/robustness of evidence in support of, or against, a given conclusion for each particular line.

Other risk assessments can address more general questions (e.g., what product/source is the likely cause of illness outbreak y?). In such instances, some lines of evidence, such as epidemiological data, can be assessed based on specific criteria such as strength of association, consistency, specificity, temporality, biological gradient/ dose-response, plausibility, coherence, experimental evidence, and analogy (e.g., the Bradford Hill (1965) criteria for causal inference). Depending on the context of the particular line of evidence involved, other criteria not described here could also be applicable. The assessment can be quantitative, by assigning a weight or value to each line of evidence assessed, in the form of probabilities, alphanumeric values, or qualitative by descriptions such as “weak” or “strong”, or implicit, in the form of logic models and decision trees that by default emphasize the importance of certain lines of evidence over others.

Assigned values or descriptions reflect the relative “strength” of a particular line of evidence, which is negatively impacted by the uncertainty and variability in datasets contributing to each line of evidence. Departmental documents elaborating on uncertainty and/or variability include, but are not limited to: *A Framework for the Application of Precaution in Science-based Decision Making about Risk* (Privy Council Office, 2003) and the *Health Products and Food Branch’s Guide for Conducting Health Risk Assessments in Humans* (Health Canada, 2011).



## 4.5 INTEGRATING MULTIPLE LINES OF EVIDENCE

The determination of the relative contributions of various lines of evidence to the overall conclusion can be performed in a single step, qualitative process, using best professional judgment. More systematic methods of quantitative integration can also be employed, where scores for individual lines of evidence may be adjusted by weighting factors that reflect the relative importance of a line within the overall body of evidence, and then mathematically integrated into a final value. However, scoring is not easily applicable in a context such as risk assessment, due to the large complexity of the different sources of information available.

The integration of values/weights is an iterative process that is repeated at many levels: within individual studies, across similar studies into a collective value for a particular line of evidence, and across multiple lines of evidence into an overall risk assessment conclusion or recommendation. For example, to determine whether a compound affects the liver, one collectively examines and integrates clinical chemistry findings along with organ weight and histopathology data within a single study, or across multiple similar studies (e.g., to assess dose-response). For integration across collection of studies for a given assessment endpoint (e.g., whether a compound is carcinogenic) one can collectively examine and integrate carcinogenicity studies, genotoxicity studies and mechanistic data. For conclusions regarding overall risk, it is necessary to integrate lines of evidence related to hazard and exposure. Further integration of human health risk and environmental risk may contribute to an overall risk profile.

## 5. Application at Health Canada

Assessment of scientific evidence is a crucial component of risk assessment and decision making at Health Canada. Moreover, for many of the regulatory programs in the Department, risk assessment conclusions (referred to as risk characterization) are often made based on the likelihood of association between a particular substance/activity and associated health effects. In this context, a WoE approach is frequently cited as the basis on which conclusions are made using the best available information to date that can be gathered, assessed, and integrated using various qualitative and quantitative methods.

The mandate and scope of risk assessment and/or risk management activities of the various programs vary significantly across the Department (see *A Primer on Scientific Risk Assessment at Health Canada*, Saner, 2010). Each program operates within the constraints of program-specific legislation. Differences in legislation and program goals impact time available for assessment of each particular product or activity, the amount and quality of information that is available to date for assessment, and



the degree of flexibility in interpretation and application of WoE as a risk assessment approach. Each program is also impacted by international guidelines for specific subject areas and the sector-specific context in which regulations may be often harmonized globally. The varying issues and the context under which regulatory decisions are made, and the scope of potential risk management options and recommendations that can be explored also differ across and within programs.

A survey was conducted to determine how WoE was applied across the department. All branches surveyed responded, including the Health Products and Food Branch (HPFB), the Healthy Environments and Consumer Safety Branch (HECSB), and the Pesticide Management Regulatory Agency (PMRA). The general principles of the WoE approach are applied by most programs surveyed. Specifically, most risk assessments follow the steps of gathering and assessing individual studies and sources of evidence, assembling studies into context specific lines of evidence, and assessing and integrating multiple lines of evidence into an overall conclusion or recommendation. Most programs interpret WoE to include concepts such as the totality of evidence (i.e., the evidence to be gathered and considered), as well as the weighing of evidence (i.e., how such evidence is assessed and integrated into a final conclusion) (see Annex 2).

The application of specific criteria and tools are context specific, and are outlined in various program specific guidelines, standard operating procedures, working documents, etc. Program documents outlining application of the WoE approach have been specifically developed for such purposes when considered necessary. For example:

- *Weight of Evidence: Factors to Consider for Appropriate and Timely Action in a Foodborne Illness Outbreak Investigation* (Health Canada, Public Health Agency of Canada, and Canadian Food Inspection Agency, 2011);
- *Framework for Initiating and Conducting Risk Analysis Activities on Microbial Hazards in Food* (Health Canada, 2017);
- *Food Investigation Response Manual* (Canadian Food Inspection Agency, 2017);
- *Science Policy Note: General Exposure Factor Inputs for Dietary, Occupational, and Residential Exposure Assessments* (Health Canada, 2014)
- *Federal Contaminated Site Risk Assessment in Canada: Supplemental Guidance on Human Health Risk Assessment for Country Foods (HHRA Foods)* (Health Canada, 2010);
- *Notice to Product License Applicants—Traditional Claim Submissions: Evidence Criteria and Evidence Assessment Template* (Natural and Non-prescription Health Products Directorate, 2010);



- *Pathway for Licensing Natural Health Products used as Traditional Medicines* (Natural and Non-prescription Health Products Directorate, 2012a)
- *Pathway for Licensing Natural Health Products Making Modern Health Claims* (Natural and Non-prescription Health Products Directorate, 2012b)

Program documents of a more general nature include:

- *Health Products and Food Branch's Guide for Conducting Health Risk Assessments in Humans* (Health Canada, 2011);
- *Framework for Science-Based Risk Assessment of Micro-Organisms Regulated under the Canadian Environmental Protection Act, 1999* (Environment Canada, Health Canada, 2013);
- *All Hazards Risk Assessment Methodology Guidelines 2012–2013* (Public Safety Canada 2018)

As mentioned above, documentation on how the risk assessment is conducted and the rationale for either including or excluding certain sources of evidence is a critical component of the decision making process. Similarly, while the WoE approach is consistently applied in most risk assessments across the Department, explicit use of WoE terminology is not always documented. In some instances, WoE terminology is used, but the specific application of the WoE approach is not elaborated.

On occasion, WoE terminology is used when actually referring to levels of evidence or standards of quality of individual studies. In some instances, WoE terminology is also used in place of actual descriptions of the strength/robustness of overall conclusions/recommendations, or in place of legal terms such as preponderance of evidence, which simply means more likely than not.

The majority of risk assessment reports, however, provide a logical narrative description of the relative strengths or weaknesses of various lines of evidence considered. For most risk assessments, individual lines of evidence are pooled and integrated into a final conclusion based on best professional judgment, and not mathematical formula. Narrative descriptions of the rationale for such judgments are usually provided, including explanations of how certain lines of evidence are more important than others in determining the overall risk assessment conclusion/recommendation. Some reports, however, simply list lines of evidence assessed and proceed directly to the overall risk assessment conclusion, without explicit documentation of how the multiple lines of evidence relate to one another, or the rationale behind the integration process.



## 6. International context

The WoE approach is routinely applied by most scientific risk assessment agencies internationally and while several definitions for WoE exist, there is no single, universal standardized/commonly agreed upon definition or specific guidance on how to implement a WoE approach. For example, recent guidance on the use of the WoE approach and “totality of evidence” has been published by the European Food Safety Authority’s Scientific Committee (EFSA, 2017a), which stated that “*weight of evidence assessment is a process in which evidence is integrated to determine the relative support for possible answers to a scientific question. The term ‘weight of evidence’ on its own is the extent to which evidence supports possible answers to a scientific question.*”

The United States Environmental Protection Agency (EPA, 2003) outlines WoE in various guidelines, in both the totality of evidence context, and the methodological context of the weighing of multiple lines of evidence, e.g.:

*“The weight-of-evidence approach considers all relevant information in an integrative assessment that takes into account the kinds of evidence available, the quality and quantity of the evidence, the strengths and limitations associated with each type of evidence and explains how the various types of evidence fit together.”*

However, in a review of the EPA’s Integrated Risk Information System (IRIS) process, the National Research Council (2014) found that:

*“systematic review and weight-of-evidence analysis have historically been described in various ways, and the terms are sometimes used interchangeably; this vagueness in use of terminology results in some confusion as to what the terms mean in practice... The committee views weight-of-evidence analysis as a judgment-based process for evaluating the strength of evidence to infer causation. However, it found that the phrase as used in practice has become too vague and is of little scientific use. An IRIS assessment must come to a judgment about whether a chemical is hazardous to human health and must do so by integrating a variety of lines of evidence. Therefore, the committee found the term evidence integration to be more useful and more descriptive of the process that occurs after completion of systematic reviews.”*

Similarly, the U.S. Environmental Protection Agency’s National Center for Environmental Assessment (2015) takes an integrated approach to science assessments for reviews of national ambient air quality standards:



*“The U.S. EPA integrates the evidence from across scientific disciplines or study types and characterizes the weight of evidence for relationships... drawing upon the results of all studies judged of adequate quality and relevance per the criteria... consider aspects, such as strength, consistency, coherence, and biological plausibility of the evidence, and develop causality determinations on the nature of the relationships... includes evaluating strengths and weaknesses in the overall collection of studies across disciplines.”*

The European Chemicals Agency (ECHA, 2011 and 2016) outlines interpretations regarding the methodological context of weighing evidence as follows:

*“The weight of evidence approach commonly refers to combining evidence from multiple sources to assess a property under consideration. It can therefore be a useful technique where, for example, each piece of information or test alone is not sufficient to address a standard information requirement but where it may be possible to combine the strengths and weaknesses of the individual studies to reach a conclusion for a particular property.*

*The term weight of evidence (WoE) is neither a scientifically well-defined term nor an agreed formalised concept characterised by defined tools and procedures. It can, however, be regarded as an evidence-based approach involving an assessment of the relative weights (values) of different pieces of the available information that have been gathered. Application of this concept can be achieved either in an objective way by using a formalised procedure or by using expert judgement. Factors such as the quality of the data, consistency of results, nature and severity of effects, relevance of the information will have an influence on the weight given to the available evidence.”*

This concept of weighing evidence is supplemented by the totality of evidence concept within the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (ECHA, 2017):

*“There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion.*

*There may be sufficient weight of evidence from the use of newly developed test methods, not yet included in the test methods referred to in Article 13(3) or from an international test method recognised by the Commission or the Agency as being equivalent, leading to the conclusion that a substance has or has not a particular dangerous property.*

*Where sufficient weight of evidence for the presence or absence of a particular dangerous property is available:*

- further testing on vertebrate animals for that property shall be omitted,*
- further testing not involving vertebrate animals may be omitted.*

*In all cases adequate and reliable documentation shall be provided.”*



The World Health Organization's International Programme on Chemical Safety has published two guidance documents regarding uncertainty in risk assessment: *Uncertainty and Data Quality in Exposure Assessment* (WHO, 2008), which explicitly addresses WoE: *"to the extent possible, the combined effect of different sources of uncertainty on the exposure or risk predictions, perhaps based on a weight-of-evidence methodology in the absence of quantitative data, should also be considered"*, and a *Guidance Document on Evaluating and Expressing Uncertainty in Hazard Characterization* (WHO, 2017).

The Food and Agriculture Organization of the United Nations and the World Health Organization (FAO/WHO, 2009) discussed using a WoE approach to the risk characterization of microbiological hazards in food: *"the weight of evidence should be evaluated according to clearly specified, scientific criteria. As more criteria are satisfied, the weight of evidence indicates a more credible risk."* FAO/WHO anticipated that *"weight-of-evidence determinations will become increasingly prominent in risk assessments of microbiological pathogens in food."*

The Organisation for Economic Co-operation and Development (OECD, 2015, 2017, 2018) defines WoE as *"a comprehensive, integrated, often qualitative judgment of the extent and quality of information supporting an hypothesis for which the approaches and tools vary, depending on the context."* WoE methodology is used in their "Adverse Outcome Pathway (AOP)/Mode Of Action (MOA)" framework for the development and use of "Integrated Approaches to Testing and Assessment" (IATA):

*"Evaluation of existing information or generation of additional data within an IATA can be performed on the basis of a non-formalised Weight of Evidence (WoE) approach or by using predefined, structured approaches such as Sequential Testing Strategies (STS), Integrated Testing Strategies (ITS) or their combination."*

In considering the use of a WoE approach, Codex Alimentarius (2014) cautions that *"The weight of evidence integrating quantitative and qualitative data may permit only a qualitative estimate of risk."*

Taken together, the above definitions from key international partners are consistent with current Health Canada interpretations of the WoE approach.



## 7. Conclusions

While specific tools and methodologies are often context-specific to particular program areas, the underlying principles of the WoE approach, in which multiple sources of information are gathered, assessed, and integrated into an overall conclusion, are commonly applied across the Department, and are judged to be consistent with international practice.

Presently, inconsistencies occur not in the high level applications of the overall WoE approach. Rather, they result when WoE terminology is applied when actually dealing with standards of quality of individual studies or strength of overall conclusions/recommendations.

Given the context specific nature of each risk assessment and the diversity of tools and criteria applicable, transparent documentation of the specific application of the WoE approach is especially important. There are opportunities for harmonization, and adherence to a simple checklist is a step towards this goal (see Annex 3). Program areas are encouraged to take the relevant steps (e.g., updating internal guidelines) to further improve the documentation aspect in reports that provide the risk assessment in support of subsequent risk management options/regulatory decision, which includes elaborating on what is meant by WoE, when necessary. Additionally, graphically based evidence maps, profiles, or tables may be helpful as supplementary tools for communication from risk assessors to risk managers.



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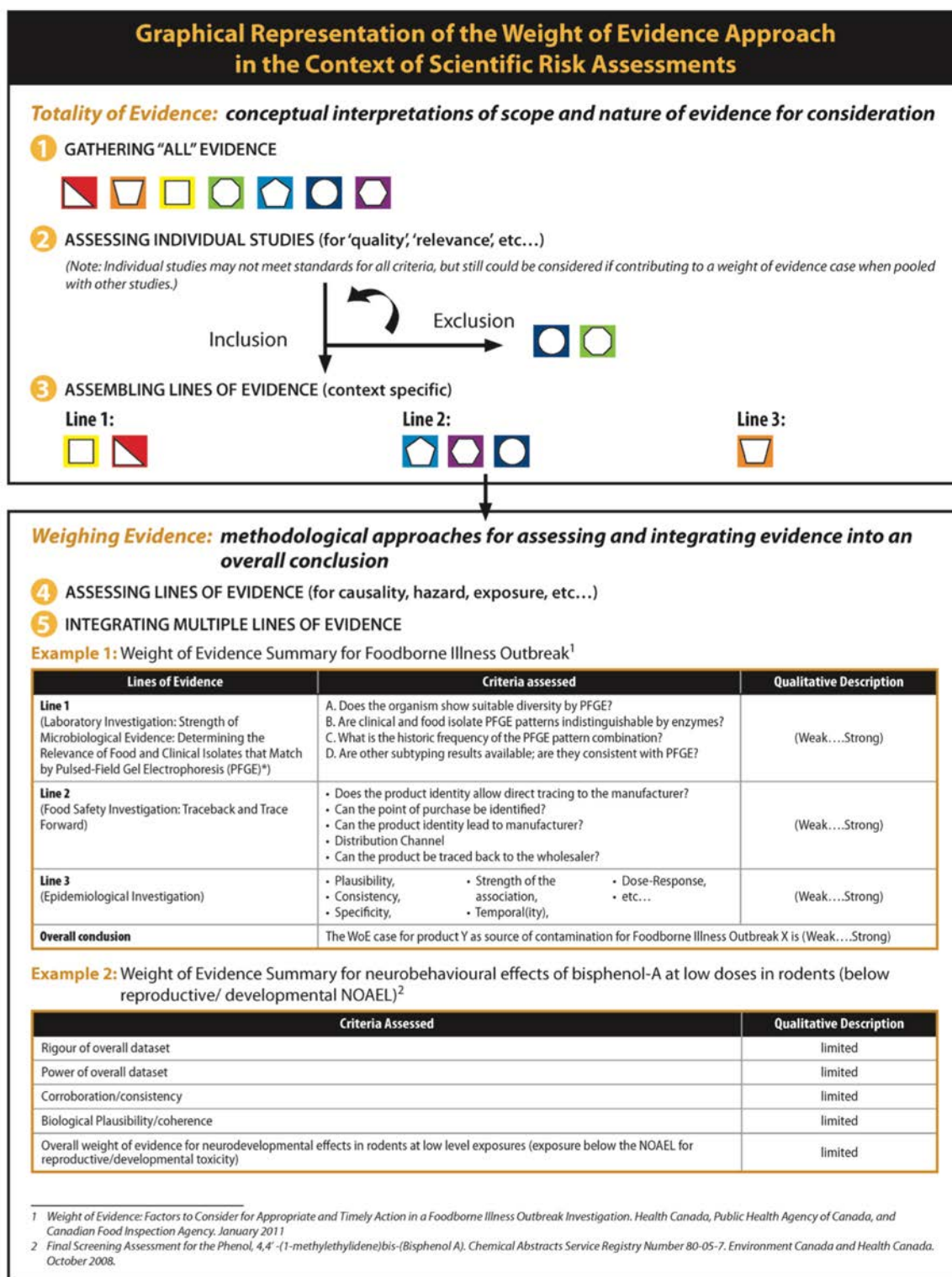
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## Annex 1





## Annex 2

### Working level interpretation(s)/application(s) of Weight of Evidence

PROGRAM	<b>TOTALITY OF EVIDENCE<sup>*</sup></b> : Conceptual interpretations of the nature and scope of evidence sources for consideration		<b>WEIGHING EVIDENCE<sup>**</sup></b> : Methodological approaches for the assessment and integration of multiple lines of evidence to derive at a final conclusion		
	Consideration of all available lines of evidence to date, as opposed to a subset of data	Consideration of studies that individually may not meet standards for all criteria, but contributing to a weight of evidence case when pooled with other studies	Qualitative (e.g., listing, best professional judgment)	Semi-quantitative (e.g., causal criteria, logic models, alphanumeric scoring or indexing)	Quantitative (e.g., probabilistic tools or Multi-Criteria Decision Analysis [MCDA])
<b>Healthy Environments and Consumer Safety Branch (HECSB)</b>					
WAQB <sup>1</sup> / Water	✓	✓	✓	✓	
WAQB / Air	✓	✓	✓	✓	
New Substances – NSACB <sup>2</sup>	✓	✓	✓		
Existing Substances – ESRAB <sup>3</sup>	✓	✓	✓	✓	
ERHSD <sup>4</sup>			✓	✓	
CPSD <sup>5</sup>	✓	✓	✓		✓
<b>Health Products and Food Branch (HPFB)</b>					
TPD <sup>6</sup>	✓	✓	✓	✓	✓
BGTD <sup>7</sup> / Biologics	✓	✓	✓	✓	✓
MHPD <sup>8</sup>	✓	✓	✓	✓	✓
NNHPD <sup>9</sup>	✓	✓	✓	✓	
VDD <sup>10</sup>	✓	✓	✓	✓	✓
FD <sup>11</sup> / Novel Foods	✓	✓	✓		
FD / Nutrition Labelling and Claims		✓			
FD / Microbial Hazards	✓	✓	✓	✓	✓
<b>Pesticide Management Regulatory Agency (PMRA)</b>					
HED <sup>12</sup>	✓	✓	✓	✓	✓

<sup>1</sup> Water and Air Quality Bureau, Safe Environments Directorate (SED)

<sup>2</sup> New Substances Assessment and Control Bureau, SED



- <sup>3</sup> Existing Substances Risk Assessment Bureau, SED
- <sup>4</sup> Environmental and Radiation Health Sciences Directorate
- <sup>5</sup> Consumer Product Safety Directorate
- <sup>6</sup> Therapeutic Products Directorate
- <sup>7</sup> Biologics and Genetic Therapies Directorate
- <sup>8</sup> Marketed Health Products Directorate
- <sup>9</sup> Natural and Non-prescription Health Products Directorate
- <sup>10</sup> Veterinary Drugs Directorate
- <sup>11</sup> Food Directorate
- <sup>12</sup> Health Evaluation Directorate

\* In general, the totality of evidence concept does not involve any actual “weighing” of multiple lines of evidence relative to each other, and is thus not interpreted as part of the WoE concept by certain programs. Nevertheless, this concept is commonly recognized as part of the scope of the WoE approach in the risk assessment context by most programs across the Department. Some differences are also observed regarding the sub-concept of considering “all” available evidence and such apparent differences may be the result of more literal interpretations of “all” available evidence by these programs compared to others, rather than a true reflection of actual differences of risk assessment practices. Moreover, a precise interpretation of “all” is also dependent on the program area/regulatory requirements in terms of the type of evidence that are required in order to support a submission. For example, for programs conducting risk assessments on therapeutic products such as drugs and biologics, the requirements come from guidelines of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). On the other hand, pesticide evaluations utilize guidance lists of required and conditionally required data, which differ depending on how and where the product is used.

\*\* Qualitative methods of assessing and integrating multiple lines of scientific evidence in Departmental risk assessment programs seem to be the dominant application of the WoE approach for risk assessments across the Department. Specific qualitative methods can range from simple listing of the evidence assessed, to more detailed narrative descriptions that explain the rationale behind the application of best professional judgment, in which some lines of evidence are considered more important, and are given more weight, compared to others. Semi-quantitative methods include systematic assignment of alphanumeric scores for each line of evidence, as well as logic models, decision trees and causality analysis that implicitly give more weight to certain lines of evidence over others, even if actual numeric scores are not assigned. Frequently referred to as “levels of evidence”, scoring tools are more often applied by programs involved in the regulation of therapeutic products, for which such standards and scoring systems exist, and are practiced, by international counterparts. Semi-quantitative methods employing hierarchal descriptors instead of alphanumeric scores are frequently employed in the context of assigning value to causality criteria used in foodborne illness outbreaks. Similarly, semi-quantitative descriptors for key events could be used for Mode of Action (MoA) assessment of chemicals for carcinogenicity/mutagenicity. Quantitative methods are not widely used across the Department, often due to limitations in availability of appropriate data.



## Annex 3

### Checklist for Transparent Documentation of Weight of Evidence Approach

When weight of evidence terminology is used, specify intended meaning in relation to the following concepts:

- ☐ ***Totality of Evidence:*** conceptual interpretations of the nature and scope of evidence sources for consideration
- ☐ ***Weighing Evidence:*** methodology for assessment and integration of multiple lines of evidence

### For the risk assessment process, are the following documented?

- ☐ evidence gathered: all available to date, individual sources and types
- ☐ evidence included for further consideration, and why (i.e., inclusion criteria)
- ☐ evidence excluded from further consideration, and why (i.e., exclusion criteria)
- ☐ lines of evidence assembled (list individual studies under each line)
- ☐ assessment criteria applied to lines of evidence, and scoring tools used (if any)
- ☐ values/weighting assigned to each line of evidence (e.g., descriptions, alphanumeric)
- ☐ integration scheme (e.g., best professional judgment, mathematical formula, criteria framework)
- ☐ overall conclusion/recommendation(s)



# Exhibit 163





## OVULATION AND RISK OF EPITHELIAL OVARIAN CANCER

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**Incessant ovulation is thought to be one of the primary causes of epithelial ovarian cancer. However, the effects of ovulation at different ages and of the various exposures or events that suppress ovulation have not been established. We used data from an Australian case-control study of 791 ovarian cancer cases and 853 controls to examine the effect of ovulation on ovarian cancer risk. The total number of lifetime ovulations was calculated using information provided in a monthly contraceptive/reproductive calendar, as well as incorporating other information such as average menstrual cycle length. An increase of 1 year's worth of ovulation was associated with a 6% increase in risk of ovarian cancer (95% confidence interval [CI] = 4–8%). Ovulations in the 20–29-year age group were associated with the greatest risk, with a 20% increase in risk associated with each year of ovulation during this age period (95% CI = 13–26%). When the effects of different exposures that suppress ovulation were compared, there was an indication that some factors may have a greater effect than others. These findings support the theory that incessant ovulation is a major contributor to the occurrence of ovarian cancer and suggest that ovulations during the 20s may be those most associated with disease risk.**

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**Key words:** ovarian cancer; case-control study; ovulation; pregnancy; oral contraceptive pill

In 1971, Fathalla was the first to suggest a possible relation between the frequency of ovulation and the development of malignant neoplasms from the ovarian epithelium.<sup>1</sup> He noted that societal developments had rendered most ovulations purposeless and proposed that repeated minor trauma to the epithelial surface of the ovary, caused by incessant ovulation, is a major risk factor for ovarian cancer.<sup>1</sup>

Various biologic findings support the “incessant ovulation” hypothesis. The ovarian epithelial cells proliferate following ovulation, which may propagate mutations or promote carcinogenesis,<sup>2</sup> and ovulation itself has been implicated in malignant transformation of the epithelium.<sup>3</sup> In support of this hypothesis is epidemiologic evidence that exposures that suppress ovulation, such as the oral contraceptive pill (OCP) and pregnancy, reduce occurrence of ovarian cancer.<sup>4</sup> In addition, a number of investigators have reported a significant association between increasing number of calculated lifetime ovulations and risk of ovarian cancer.<sup>4–12</sup> In general, however, the number of accumulated lifetime ovulations has only been crudely estimated by subtracting duration of pregnancies, lactation and OCP use from the total years between menarche and menopause.

Using data from a large Australian population-based case-control study, we have explored the relationship between ovulation and risk of ovarian cancer in greater depth. In addition to comparing the separate effects of the most common exposures/events that suppress ovulation, we have considered the effects of age-specific ovulations on risk of ovarian cancer.

### MATERIAL AND METHODS

Histologically confirmed incident cases of primary epithelial ovarian cancer registered in major gynecologic-oncology treatment centres in 3 Australian states were ascertained. Notification of cancer cases is obligatory in Australia; however, only in Queensland could the cancer registry be accessed to ensure complete case ascertainment. In the other 2 states, approximately half

of eligible cases notified to the registry were enrolled. Cases diagnosed in 1991 and 1992 in New South Wales and Victoria and from August 1990 to the end of 1993 in Queensland were recruited. Histologic diagnosis was confirmed by an independent gynecologic pathologist in each state. Details have been published elsewhere.<sup>13</sup> Briefly, ovarian cancer patients who were aged 18–79 years at diagnosis and capable of completing the questionnaire were eligible to participate. A control series was selected at random from the electoral roll (enrollment to vote is compulsory in Australia), frequency-matched to cases on broad geographic region and weighted so that the age distribution would match that of the cases. Women with previous ovarian cancer or bilateral oophorectomy or those incapable of completing the questionnaire were not eligible; cases found not to be on the electoral roll were also excluded from the analysis.

Identically trained interviewers administered a standard questionnaire to each woman in a face-to-face interview to obtain personal details including marital status, level of education, height and weight, smoking history, history of abdominal surgery, talc use, menstrual cycle details and family history of ovarian or other cancers. Details of each woman's reproductive and contraceptive histories were obtained by means of pregnancy and contraceptive calendars that elicited, month by month, events in the woman's reproductive life from age 15–50 years. In a small number of calendars, some missing data were filled in by parallel information gathered in the questionnaire.

### Estimating lifetime ovulations

The length of time a woman had ovulated up to the age of diagnosis (or interview for controls) was calculated using age at menopause for postmenopausal women or current age for premenopausal women, age at menarche, total duration of pregnancies (births and abortions), duration of OCP use, postpregnancy amenorrhoea, other periods of amenorrhoea, menstrual cycle length and average ovulatory intensity across reproductive life as reported by Metcalf *et al.*<sup>14</sup> Women were classified as premenopausal if they were still menstruating and were not on hormone replacement therapy (HRT) and as postmenopausal if their periods had ended naturally. If they reported a surgical menopause via hysterectomy, age at natural menopause was estimated as the age they began HRT or first had menopausal symptoms or at age 50 (the mean age of natural menopause for both cases and controls).

Pregnancies of <20 weeks gestation were classified as abortions (spontaneous or induced) and those ≥20 weeks as births (still or live).<sup>15</sup> After each pregnancy, the reported number of weeks before

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periods returned was cumulated to estimate duration of “postpregnancy amenorrhoea.” If women could not recall this, it was estimated using duration of breastfeeding (without supplementation), up to a maximum of 12 months,<sup>16</sup> or for those who did not breastfeed, it was taken to be 6 weeks after births or 3 weeks after abortions (including ectopic pregnancies).<sup>17</sup> Women were also asked the length of time their periods had ever stopped due to chronic illness, psychological stress, excessive leanness, obesity or post-OCP use, all referred to as “other amenorrhoea.”

For each woman, the total potential ovulatory time in months was multiplied by the average number of menstrual cycles per month (calculated from her reported menstrual cycle length) to estimate the cumulative number of ovulations that occurred during her lifetime up to the time of diagnosis/interview. Months of pregnancy, OCP use, postpregnancy amenorrhoea and other amenorrhoea were similarly weighted to estimate the cumulative number of ovulations suppressed. Results are presented as equivalent year's worth of ovulation (ovulatory years) by dividing total ovulations by 13 (since a normal 28-day cycle constitutes 13 ovulations per year).

The number of ovulations occurring at various ages during a woman's reproductive life was also considered. Specifically, ovulations accumulated from ages 10–19, 20–29, 30–39 and 40–49 years were analysed separately, and the risks associated with increasing number of ovulations in each age band were compared. Since the incidence of ovulation varies by age,<sup>14</sup> estimates of the age-specific incidence of ovulation per menstrual cycle were used to weight the number of cycles at different ages and allow valid comparison of the risk estimates across various ages. The exact weights used to adjust menstrual cycles, based on the average incidence of ovulation reported by Metcalf *et al.*,<sup>14</sup> were 56.5%, 84%, 98%, 90.5% and 66% for the age periods 10–19, 20–29, 30–39, 40–49 and  $\geq 50$  years, respectively.

#### Statistical analysis

Crude odds ratios (OR) with 95% confidence intervals (CI) were used as unadjusted measures of association between levels of exposures and disease status. Unconditional logistic regression was carried out to estimate the effect of ovulation and of exposures that suppress ovulation after adjusting for age and age squared (in years), level of education, residential location (state; urban vs. rural), talc use in the perineal region, body mass index (BMI), smoking status (current, past, never), family history of breast or ovarian cancer and a previous hysterectomy or tubal sterilization.<sup>13</sup> For the investigation of ovulations at different ages, ORs were also adjusted for the number of ovulations at other ages, since ovulations in each age band were correlated. Wald  $\chi^2$  statistics were calculated to test for homogeneity of regression coefficients to assess whether greater risk was associated with a particular form of anovulation or ovulations occurring within a particular age period. All analyses were conducted using SAS for Windows release 8.2 (SAS Institute, Cary, NC).

#### RESULTS

Of 1,116 cases of epithelial ovarian cancer identified, 191 (17%) were ineligible on grounds of age, language problems, mental incapacity or histology; 50 (4%) died prior to interview; 12 (1%) were unable to be contacted; 41 (4%) either refused or their doctor did not consent; and 29 (3%) were excluded because they were not on the electoral roll. Among 1,527 potential controls selected from the electoral roll, 192 women (13%) could not be traced; 162 (11%) were ineligible or physically unable to participate; and 318 (21%) refused. A further 2 cases and 2 controls were excluded from the analysis because of insufficient information in their pregnancy and contraceptive calendars. After exclusions as described above, there were 791 eligible cases and 853 eligible controls who provided adequate data for calculation of total ovulations.

#### Total number of lifetime ovulations

The cumulative number of ovulatory years ranged from 0–42; for cases the mean number was 22.1 (SD = 8.2) and for controls 19.5 (SD = 8.8), a difference that was statistically significant ( $t = 6.3$ ;  $df = 1,644$ ;  $p < 0.001$ ). Thus, on average, cases had 2–3 more ovulatory years than did controls.

Ovulatory years were grouped into 10-year bands, and the resulting distributions for cases and controls compared (Table I). There was a significant trend of increasing risk of epithelial ovarian cancer with increasing number of years of ovulations ( $p < 0.001$ ), particularly after adjusting for confounding factors such as age. Women with  $\geq 30$  years of ovulations had more than 5 times the adjusted risk of ovarian cancer of women with fewer than 10 years of ovulations (OR = 5.01, 95% CI = 2.86–8.76). Using years of ovulations in the model as a continuous variable resulted in an OR of 1.06 per ovulatory year (95% CI = 1.04–1.08), indicating a 6% increase in risk of ovarian cancer associated with each full ovulation year a woman experienced.

The effect of ovulation was similar for women with both borderline ( $n = 138$ ) and frankly malignant ovarian tumours ( $n = 653$ ). There also was a nonsignificant 4% increase in the risk of primary peritoneal tumours associated with each year of ovulation, although there were only 22 cases with these tumours (all malignant), so the confidence interval for this effect was wide (OR = 1.04, 95% CI = 0.96–1.13). Among histologic subtypes of epithelial ovarian cancer, adjusted ORs for each ovulatory year were 1.06 for serous tumours (95% CI = 1.04–1.08), 1.10 for endometrioid tumours (95% CI = 1.06–1.14), 1.08 for clear cell tumours (95% CI = 1.03–1.13), 1.01 for mucinous tumours (95% CI = 0.98–1.04), 1.03 for undifferentiated tumours (95% CI = 0.97–1.07) and 1.11 for mixed epithelial/mixed mesodermal tumours (95% CI = 1.06–1.17). As reported previously from our data,<sup>18</sup> the risk associated with ovulation appears to be restricted to nonmucinous tumours.

#### Timing of ovulations

Crudely, for each age period, a greater number of ovulations was associated with an increasing risk of ovarian cancer (Table

TABLE I—NUMBER OF LIFETIME OVULATIONS FOR CASES (INVASIVE AND BORDERLINE) AND CONTROLS

Years of ovulation	Cases ( $n = 791$ )	Controls ( $n = 853$ )	Crude OR (95% CI)	Adjusted OR <sup>1</sup> (95% CI)
0–9 years	10.0%	16.3%	1.0	1.0
10–14 years	10.9%	15.9%	1.11 (0.76–1.64)	1.53 (0.96–2.44)
15–19 years	13.7%	14.7%	1.51 (1.03–2.20)	2.34 (1.44–3.78)
20–24 years	20.1%	19.9%	1.64 (1.15–2.32)	2.52 (1.57–4.07)
25–29 years	33.6%	26.4%	2.07 (1.49–2.88)	3.29 (2.03–5.31)
30–42 years	11.9%	6.8%	2.85 (1.86–4.38)	5.01 (2.86–8.76)
OR per ovulatory year				1.06 (1.04–1.08)

<sup>1</sup>OR, odds ratio; CI, confidence interval.—ORs adjusted for age, age squared, education, area of residence, body mass index (BMI), talc use in perineal region, smoking status, tubal sterilization, hysterectomy and a family history of breast or ovarian cancer.



II). After controlling for ovulations in other age periods however, the 20–29-year age period had the most distinct trend of increasing risk with increasing number of ovulations, there being a 20% increase in risk associated with each ovulatory year accumulated in this age period (OR = 1.20, 95% CI = 1.13–1.27). There was a 6% increase in risk associated with each ovulatory year during the 30–49-year age period, after controlling for ovulations in the younger age periods. An increased number of ovulations in the 10–19-year age band had a nonsignificant inverse association with risk of disease after controlling for ovulations in other age periods ( $p = 0.21$ ). A test for homogeneity of regression coefficients revealed significantly different effects of ovulations in the various age periods ( $p < 0.001$ ).

#### Comparison of different anovulation mechanisms

Risk estimates were obtained for each type of event associated with ovulation suppression, mutually adjusted for each other, as well as for other potential confounders. Use of the OCP was associated with an 8% decrease in risk of ovarian cancer with each year of ovulation suppressed (OR = 0.92, 95% CI = 0.89–0.94); births a 12% decrease in risk (OR = 0.88, 95% CI = 0.78–0.98); postpregnancy amenorrhoea a 13% decrease in risk (OR = 0.87, 95% CI = 0.72–1.05); other amenorrhoea a 4% reduction in risk (OR = 0.96, 95% CI = 0.70–1.30); and abortions showed a 35% increase in risk with each year of associated anovulation (OR = 1.35, 95% CI = 0.73–2.48). All of the events/exposures, except for abortion, showed trends of decreasing risk with increasing years of ovulation suppression (although even the effect of abortions was not inconsistent with the other effects, taking into consideration the width of the confidence interval). The test for homogeneity of regression coefficients did not indicate any significant difference in effects ( $p = 0.53$ ). The OCP, based on sufficient exposure, was the only one to show a clear trend with long-term suppression of ovulation. The effect associated with the OCP was very similar in nulligravid women (OR per year = 0.91, 95% CI = 0.85–0.98) to that seen in gravid women (OR per year = 0.92, 95% CI = 0.89–0.94).

#### DISCUSSION

A number of prior epidemiologic studies have attempted to estimate women's total duration of ovulatory life based on their reproductive and contraceptive histories. All have shown that the relative risk of ovarian cancer increases significantly by 2–4.5-fold with >35 years of ovulation compared to <25 years.<sup>4–12</sup> A linear relationship between increasing years of ovulation and risk of disease has also been noted by some.<sup>8,9,11</sup> The approach to investigating the role of ovulation in the development of ovarian cancer taken here was similar in principle to the approaches of previous studies, but we attempted to refine calculations further by taking into account underlying biologic influences on ovulation. To this end, a more precise definition of age at menopause was used, especially post hysterectomy, using information on menopausal symptoms and treatment to estimate age at cessation of ovulation. In addition, anovulation due to amenorrhoea caused by factors such as psychologic stress or chronic illness was considered, and the calculation of total potential number of ovulations was tailored to the actual length of each woman's menstrual cycle. Finally, since information was collected by means of a lifetime calendar, the timing of ovulation could be examined and adjustments made for variations in frequency of ovulation at various ages. However, any approach to calculating number of ovulations will be imprecise because not all seemingly normal cycles are ovulatory and this varies from woman to woman. In addition, the various mechanisms for suppression of ovulation are not likely to be recalled with equal accuracy. Number of births, for instance, is likely to be recalled more accurately than periods of amenorrhoea. The accuracy of recall is unlikely to differ between cases and controls, leading to a greater attenuation of the effect of some mechanisms than others. A recent article comparing various methods for calculating numbers of lifetime ovulations concluded that it is important to assess the various mechanisms separately because their effects are not homogenous.<sup>19</sup>

Risk of ovarian cancer in this Australian population appeared to be related to the number of lifetime ovulations in a linear fashion (Table I), with an average 6% increase in risk associated with each ovulatory year. This finding supports a model proposed by Pike,<sup>20</sup> which relates incidence of ovarian cancer to duration of exposure

TABLE II – YEARS OF OVULATION WITHIN AGE BANDS FOR CASES AND CONTROLS

Years of ovulations within age bands	Cases (n = 791)	Controls (n = 853)	Adjusted OR <sup>1</sup> (95% CI)	Adjusted OR <sup>2</sup> (95% CI)
Age 10–19 years				
< 4 years	70.2%	71.9%	1.0	1.0
4–5 years	27.7%	26.1%	1.05 (0.84–1.33)	0.95 (0.75–1.20)
6–8 years	2.0%	2.0%	1.16 (0.56–2.41)	0.73 (0.34–1.56)
OR per ovulatory year			1.05 (0.96–1.15)	0.94 (0.85–1.04)
Age 20–29 years				
< 4 years	21.8%	34.8%	1.0	1.0
4–5 years	20.0%	20.6%	1.75 (1.27–2.41)	1.65 (1.19–2.29)
6–7 years	37.7%	31.6%	2.20 (1.62–3.00)	1.98 (1.42–2.77)
8–11 <sup>3</sup> years	20.4%	13.0%	3.04 (2.11–4.37)	2.79 (1.87–4.15)
OR per ovulatory year			1.20 (1.14–1.27)	1.20 (1.13–1.26)
Age 30–39 years				
< 4 years	18.0%	26.8%	1.0	1.0
4–5 years	9.7%	12.5%	1.29 (0.86–1.93)	1.35 (0.90–2.04)
6–7 years	15.5%	13.3%	1.96 (1.34–2.86)	1.60 (1.08–2.37)
8–13 <sup>3</sup> years	56.8%	47.4%	1.96 (1.44–2.67)	1.44 (1.03–2.01)
OR per ovulatory year			1.10 (1.06–1.14)	1.06 (1.02–1.10)
Age 40–49 years				
< 4 years	33.8%	41.9%	1.0	1.0
4–5 years	14.4%	14.6%	1.22 (0.87–1.71)	1.25 (0.88–1.77)
6–7 years	13.1%	11.3%	1.57 (1.09–2.24)	1.34 (0.92–1.95)
8–11 <sup>3</sup> years	38.7%	32.2%	1.59 (1.19–2.13)	1.31 (0.96–1.78)
OR per ovulatory year			1.07 (1.04–1.11)	1.04 (1.00–1.09)

<sup>1</sup>ORs adjusted for age, age squared, education, area of residence, body mass index (BMI), talc use in perineal region, smoking status, tubal sterilization, hysterectomy and a family history of breast or ovarian cancer. <sup>2</sup>ORs also adjusted for number of ovulatory years in other age periods. <sup>3</sup>Due to short cycle lengths, some women had the equivalent of more than one ovulatory year in a calendar year.



of the ovarian epithelium to ovulation. Support for a direct role of ovulation on ovarian tumour development also comes from animal studies that have shown that, when continuously hyperovulated, domestic laying hens develop high rates of ovarian tumours,<sup>21</sup> and mice ovarian epithelium undergoes neoplastic changes.<sup>22</sup>

Within all decades of reproductive life after 20 years of age, cases had a significantly higher number of age-specific ovulations than did controls, with ovulations occurring from 20–29 years of age incurring a markedly greater risk of ovarian cancer than those occurring at any other time. The 20–29-year age period is the time when ovulations are most commonly interrupted by contraceptive and reproductive exposures and so is likely to show the most variation between cases and controls with respect to number of ovulations. This association could also suggest, however, that ovulations in the 20–29-year age group are the most influential in terms of development of ovarian cancer, reflecting the “induction time” between disease initiation and detection.<sup>23</sup> It is likely that ovarian cancer has a reasonably long latency period between initiation and manifestation of established disease, and this is exacerbated by the usually late clinical detection of the disease. The peak incidence of ovarian cancer is in the 60–70-year age period,<sup>24</sup> which was also seen in the series of cases in our study. If ovulation has the greatest effect during a woman’s 20s, it would suggest that an increased number of ovulations during this age period may increase the risk of disease initiation. Thus, the latency period of more advanced, malignant epithelial ovarian cancer could be estimated to be approximately 30–40 years. This time frame is consistent with data from the Hiroshima cohort, which estimated a minimum radiation-induced latency period of 15–20 years for ovarian cancer development.<sup>25</sup> The increase in risk associated with ovulations during the 30–49-year age period may indicate that either ovulation itself or the repeated exposure to gonadotrophins associated with ovulation could promote disease development during this period. If the role of ovulation was primarily promotion of already initiated disease, risk would be highest at ages closer to the time of usual disease detection.

The corollary to the hypothesis that ovulation initiates mutagenesis of ovarian epithelial cells is that the amount of protection afforded by exposures that suppress ovulation should be independent of the particular cause of anovulation and depend only upon the total period of anovulation. In a previous analysis of these data, Siskind *et al.*<sup>26</sup> concluded that the protective effect of the OCP was greater than what would be predicted by suppression of ovulation alone. Similarly, Risch *et al.*,<sup>10</sup> La Vecchia *et al.*<sup>9</sup> and Whittemore *et al.*<sup>4</sup> have also concluded from their data that the relationship between ovulation-suppressive events/exposures and development of disease is more complex than could be explained by duration of anovulation. In our analysis, we found a 12% reduction in risk associated with each year of ovulation suppressed through full-

term pregnancies, with corresponding risk reductions of 8% for the OCP, 13% for postpregnancy amenorrhoea and 4% for other amenorrhoea. Although there was no significant difference in the size of these effect estimates ( $p = 0.53$ ), the effects of OCP and pregnancy were larger than other forms of amenorrhoea, consistent with the previous findings and with recent evidence of a direct hormonal effect on ovarian epithelium.<sup>27</sup> Different formulations of the OCP also have recently been shown to have different effects on ovarian cancer risk;<sup>28</sup> unfortunately attempts to collect information on the type of OCP used in this study were unsuccessful. Further research is necessary into the mechanisms underlying the protective effects of pregnancy and the OCP in ovarian cancer development, other than suppression of ovulation.

Pregnancy resulting in abortions (spontaneous or induced) appeared to be associated with an increased risk of ovarian cancer, which was due to a positive association seen with induced abortions, suggesting that some other factors associated with induced abortions may increase risk over and above any protection afforded by the few suppressed ovulations. Also, because the number of ovulations suppressed by abortions was much fewer than for other factors, it was difficult to assess the magnitude of its effect to the same degree, thus uncertainty remains for this association.

Some support for a direct role of ovulation is also found among the subgroup of infertile women who suffer from anovulatory infertility. In a pooled analysis of 8 population-based case-control studies (including the one presented here), it was found that anovulatory infertility was negatively associated with ovarian cancer risk (albeit not significantly), whereas unsuccessful attempts to become pregnant were associated with an increased risk of ovarian cancer.<sup>29</sup>

In summary, our results would be consistent with initiation of ovarian epithelial carcinogenesis due to ovulation from 20–30 years of age and tumour promotion occurring after about age 30, either through the mechanism of ovulation itself or due to the high levels of hormones associated with it. These events may then culminate to result in a tumour becoming clinically apparent from the ages of 55–75 years. Clearly insights at the molecular level would help evaluate the actual role of ovulation in ovarian cancer development. Mutations of the p53 tumour suppressor gene were associated with an increased number of lifetime ovulations in one study,<sup>30</sup> but this finding was not replicated in a subset of our data.<sup>31</sup> Perhaps other gene mutations may be responsible or some other role of ovulation such as epithelial inflammation.<sup>32</sup> The exact mechanism is yet to be determined.

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